

EPA Jacket 2382-192



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

2382-192

Date of Issuance:

FEB 21 2013

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

**EFFITIX™ PLUS Topical
Solution for Dogs**

Name and Address of Registrant (include ZIP Code):

**Virbac Animal Health, Inc.
P.O Box 162059
Fort Worth, TX 76161**

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered//reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with section 3(c)(7)(A) of FIFRA provided that you:

1. Submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under section 4 of FIFRA.
2. Submit within 12 months of the date of issuance of this Registration Notice, acceptable guideline studies for Storage Stability study (OPPTS GLN: 830.6317) and Corrosion Characteristics study (OPPTS GLN: 830.6320) for this product.
3. Change the product registration number to "EPA Reg. No. **2382-192**"
(continued on page 2)

Signature of Approving Official:

See page 2

Richard Gebken, Product Manager (10)
Insecticide Branch, Registration Division (7505P)

Date:

FEB 21 2013

EPA Form 8570-6

Conditions of acceptance

1. This registration is now time-limited and expires two years from the date of this letter.
2. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning April 1, 2013.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kaitlon Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.

Report aggregate incidents, but do not combine moderate and minor incidents.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. If EPA determines that future mitigation measures are necessary for all spot-on products, the Agency will inform registrants and if needed, EPA may take regulatory action. If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10,
Insecticide Branch
Registration Division (7505P)

Enclosure: Label Stamped "with Comments"

Virbac's Master Label

Date 21 February 2013

Version US-20

EPA Reg. No. 2382-xxx

Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

2382-192

Optional Text Appears In Brackets

EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 5 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil.....	6.0%
Permethrin*	44.8%
Pyriproxyfen.....	1.8%

OTHER INGREDIENTS:	47.4%
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TOTAL:	100.0%
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* cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING :	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.	

Inside flap (single presentation insert only)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs and puppies under 8 weeks of age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

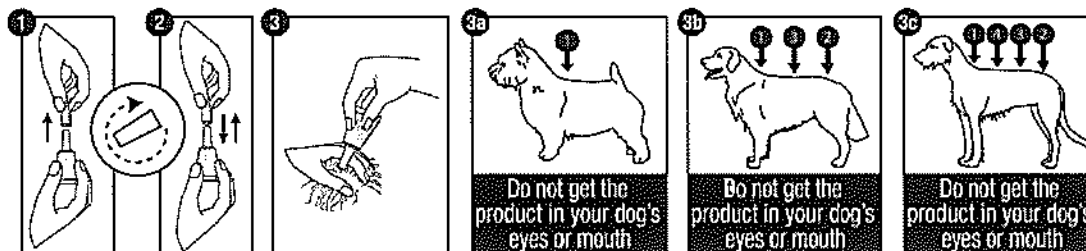
Do not apply more often than once a [per] month [every 30 days].

For use on DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs and puppies 8 weeks old or older weighing 5 to 10.9 lbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIX™ Plus Topical Solution for Dogs is not applied superficially on dog's hair.



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing] and lice infestations can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.

Fleas: EFFITIX™ Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for [up to] three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAO), or if re-infestation is likely.

Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for [up to] a month. Apply monthly where lice control is consistently needed.

Mites: EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of [sarcoptic mange]/[mite infestations that may cause sarcoptic mange].

Biting flies and Mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for up to 4 weeks [a [one] month]. Kills mosquitoes for up to four weeks [a [one] month].

Notes: Wait at least 30 days before re-application of EFFITIX™ Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap [single presentation on insert]

LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 5 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs 11 to 22.9 lbs (0.034 fl oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.068 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1mL, 2mL, 4mL or 6mL)/ 0.017 fl oz, (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (of solution).

[Detachable] calendar [monthly application] reminder stickers (with illustration of dog or puppy)

Back Panel (single presentation on side panel)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-FRA-1

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH TX 76161
1-800-338-3659

Made in France
EFFITIX™ is a trademark of Virbac S.A.
Questions or comments? Call: 1-800-338-3659.

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application
See package insert for directions for use and storage and disposal
See package insert for frequency of application and storage and disposal
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs ONLY
Use ONLY on dogs
See inside flap for directions for use

Text for Foil of Blister package

Virbac
EFFITIX™ Plus Topical Solution For Dogs
Only for use on dogs (5 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx
DO NOT USE ON CATS
CAT PROHIBITION ICON

Text for Applicator Tube

Virbac
EFFITIX™ Plus
Topical Solution For Dogs
Only for use on dogs
(5 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/
(0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) / (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
Contains fipronil (6.0%), permethrin (44.8%), and pyriproxyfen (1.8%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
DO NOT USE ON CATS
EPA Reg. No. 2382-xxx
CAT PROHIBITION ICON

MARKETING CLAIMS

(Multiple infestations)

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of sarcoptic mites, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of mites that may cause sarcoptic mange, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 5 to 10.9 lbs [0.17 fl oz] (0.5 mL), small dogs 11 to 22.9 lbs [0.034 fl oz] (1.0 mL), medium dogs 23-44.9 lbs [0.068 fl oz] (2.0 mL), large dogs 45-88.9 lbs [0.135 fl oz] (4.0 mL), and extra large dogs 89-132 lbs [0.203 fl oz] (6.0 mL).
- EFFITIX™ Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel (against) biting flies, and repel and kill mosquitoes.
- Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, [and lice] infestations

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick [biting and chewing] lice infestations, can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Helps to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

[Fleas]

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX™ Plus Topical Solution for Dogs
- Prevents all flea stages [adult fleas, flea eggs, flea pupae and flea larvae]
- Prevents development of all flea stages [flea eggs, flea pupae and flea larvae] for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen [IGR]* to break [the] flea life cycle
*insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis, [tularemia] [and tapeworm infestations]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [*Dipylidium caninum*]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills [adult] fleas [within 6 hours] that may cause Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD [Flea Allergy Dermatitis]
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to [90 days] [3 months]]
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] [however if your dog is susceptible to Flea Allergy Dermatitis [FAD] it is recommended to use monthly]
- Kills fleas, flea eggs, and flea larvae
- EFFITIX™ Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or if reinfestation is likely.
- Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides ongoing protection against fleas and the following diseases: bartonellosis, [tularemia] [and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents [Stops] re-infestations by killing adult fleas [before they lay eggs]
- Treatment with EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea [prevention] [protection] year-round

[Ticks]

- Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for [up to] at least [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], Brown dog ticks [that may transmit ehrlichiosis], and Lone Star ticks [that may transmit hepatoparasitosis] for up to one month [4 weeks]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], and Brown dog ticks [that may transmit ehrlichiosis] for up to one month [4 weeks].
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month [4 weeks].
- Kills Lone Star ticks (*Amblyomma americanum*) for 4 weeks [for up to one month].
- Effective monthly application against ticks

[Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks] [a [one] month]
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for [up to] 4 weeks [a [one] month]
- Repels and kills mosquitoes for up to four [4] weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents [inhibits] blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [[Prevents blood-feeding by] [Kills and repels]] mosquitoes
- Repels biting flies
- Repels [[annoying][bothersome][nuisance]] biting flies
- Inhibits [[annoying][bothersome] [[nuisance]] biting flies
- [[Prevents][inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos (*Culex* spp, *Dchferotatus* spp, *Aedes* spp) which may vector heartworm (*Dirofilaria immitis*) for one month

]Lice and Mites]

- Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for a [one] month. Apply monthly where lice control is consistently needed.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs] aids in [the] control of mites that may cause sarcoptic mange.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs] aids in [the] control of sarcoptic mites
- EFFITIX™ Plus Topical Solution for Dogs aids in (the) control of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of sarcoptic mange.
- Aids in [the] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- [Also] Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills [biting] [chewing] lice
- For control and prevention of [[biting] [chewing]] lice [infestations]
- Stops existing [[biting] [chewing]] lice infestations
- Prevents and controls [[biting] [chewing]] lice [infestations]
- Provides effective control of [[biting] [chewing]] lice [infestations]
- Kills [[biting] [chewing]] lice and prevents further infestations
- For control and prevention of [infestation] [[with] [[biting] [chewing]] lice

]Others)

- 1 [3, 6, 36] applicator(s) [tube(s)] 0.5 mL [1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL]
- 1 [3, 6, 36] applicator(s) [tube(s)] 0.017 fl oz [0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz]
- 1 [3, 6, 36] applicator(s) [tube(s)] 0.017 fl oz [0.5 mL], [0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL]]
- 1 [3, 6, 36] applicator(s) [tube(s)] (each) containing 0.017 fl oz [0.5mL] [0.034 fl oz] 1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL]]
- 1 [3, 6, 36] applicator(s) [tube(s)]
- 1 [3, 6, 36] monthly dose(s) [application(s)]
- 1 [3, 6, 36] applicator(s) [tube(s)] 1 [3, 6, 36] month(ly) dose(s) [application(s)]
- DO NOT USE ON CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 5 to 10.9 lbs, weighing 11 to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy and convenient application [applications]
- Remains effective for a [one] month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, [biting, chewing] lice and biting flies is prevented for a [one] month
- Convenient topical treatment for dogs

- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-]infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply] spot-on [topical] application
- Fragrance [odor] free
- No noticeable odors
- Single application lasts 4 weeks [one month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]
- EFFITIX™ Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof [remains effective after bathing and swimming] for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [[for a month] [for one month] [for up to four weeks]]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package [applicator tubes]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

BARCODE No.: 407438; DECISION No.: 468313 FILE SYMBOL No.: 2382-ROE;
PRODUCT NAME: Effitix TM Plus Topical Solution for Dogs; ;
PC Code(s): 129121, 129032 & 109701; Action Code: R310; FOOD Use: No

DATE: January 25, 2013

SUBJECT: Product Name: **Effipro Plus Topical Solution for Dogs**

FROM: Akiva Abramovitch, Ph.D.
 Technical Review Branch / RD (7505P) *J*

THROUGH: Shyam Mathur, Ph.D.
 Product Chemistry Team Leader
 Technical Review Branch/RD (7505P) *S/Bm 02-08-13*

TO: Driss Benmehend/Richard Gebken, PM 10
 Insecticide Branch/ RD (7505C)

Company Name: **Virbac**
Formulation Type: **Spot-On Solution**

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 488963-01 through -08). The CSF of the basic formulation (dated 07/15/2012) was submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed basic CSF dated October 15, 2012 and Alternate CSF #1 dated July 12, 2012.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Fipronil (6.0%), permethrin (44.8%) and Pyriproxyfen (1.8%).
2. Has the registrant claimed substantial similarity to a registered product?

[] Yes; [X] No; if yes give the registration number of the cited product.

3. All the source materials for the active ingredients are derived from the registered sources:
[X] Yes; [] No.

BARCODE No.: 407438; DECISION No.: 468313 FILE SYMBOL No.: 2382-ROE;
PRODUCT NAME: Effitix TM Plus Topical Solution for Dogs; ;
PC Code(s): 129121, 129032 & 109701; Action Code: R310; FOOD Use: No

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses: ☒ Yes; ☐ No.

5. Confidential Statement of Formula(s):

☒ Basic CSF Dated: July 12, 2012;
☒ Alternate CSF #1 Dated: July 15, 2012

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA; {name} acid equivalent = xx %

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes, ☐ No, ☒ NA, if not, explain below:

d. Label requires an additional Storage and Disposal statement:

☐ Yes ☒ No

BARCODE No.: 407438; **DECISION No.:** 468313 **FILE SYMBOL No.:** 2382-ROE;
PRODUCT NAME: Effitix TM Plus Topical Solution for Dogs; ;
PC Code(s): 129121, 129032 & 109701; **Action Code:** R310; **FOOD Use:** No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	488963-01
830.1600	Description of materials used to produce the product		X		A	488963-01
830.1650	Description of formulation process		X		A	488963-01
830.1670	Discussion on the formation of impurities		X		A	488963-01
830.1700	Preliminary analysis		X		A	488963-02
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	488963-01
		Proposed Limits			NA	
		Justification for wider limits			NA	
830.1800	Enforcement analytical method		X		A (HPLC method)	488963-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Clear yellow oderless liquid	A	488963-03
830.6315	Flammability	97.3°C flashpoint	A	488963-05

BARCODE No.: 407438; **DECISION No.:** 468313 **FILE SYMBOL No.:** 2382-ROE;
PRODUCT NAME: Effitix TM Plus Topical Solution for Dogs; ;
PC Code(s): 129121, 129032 & 109701; **Action Code:** R310; **FOOD Use:** No

830.6316	Explodability	NA, not considered to be potentially explosive	W	
830.7000	pH	6.32 1% solution at 22 C	A	488963-07
830.7300	Density (units)	1.1163 g/cm ³	A	488963-08

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
 NA = Not applicable, I = In progress, U = Upgradeable

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed CSF for the basic formulation dated July 12, 2012 and the Alternate CSF #1 dated July 15, 2012 are acceptable
2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product) , 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
3. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explodability), 830.7000 (pH), 830.7100 (viscosity), and 830.7300 (density) are acceptable.
4. The storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) studies were not submitted and will be conducted. These physical/chemical properties are required and it is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.
5. The proposed label was screened as it pertains to the product chemistry requirements. Review of the proposed label and uses are the purview of the RM team.

DATA PACKAGE BEAN SHEET

Date: 10-Dec-2012

Page 1 of 3

Decision #: 468313

DP #: (407438)

PRIA

Parent DP #:

Submission #: 921393

E-Sub #: 3261

*** Registration Information ***

Registration: **2382-ROE - EFFITIX TM PLUS Topical Solution for Dogs**

Company: 2382 - VIRBAC AH, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Driss Benmhend DBENMHEN

Sent Date: _____

PRIA Due Date: 23-Feb-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NDN-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: See page 3

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 10-Dec-2012

Due Back: _____

DP Ingredient: See page 3

DP Title: Initial application for a new spot-on product

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD/TRB

Team Name: Chem

Reviewer Name: _____

Contractor Name: _____

Last Possible Science Due Date: 24-Jan-2013

Science Due Date: _____

Sub Data Package Due Date: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Virbac has requested the registration of this fipronil/permethrin/nylar product.

I'm requesting an expedited review, as the jacket with 15 volumes of data has been missing since initially received.

Attached is the 8570-t

Transmittal letter

Basic CSF and 1 Alternate CSF.

Data Matrix

Formulator's exemption statement

Copy of proposed label.

This is the product chemistry package.

All of the studies referenced are in documentum, so there are no hard copies to send with this BEAN.

MRID	MRID Status	Citation Reference	Guideline	86.5 Status
48896301		Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/t04/t6/t1/OCR. Unpublished study prepared by Virbac. 54p.	830.1550/Product Identity and composition	Pass (14-Aug-2012)
48896301		Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/t04/t6/t1/OCR. Unpublished study prepared by Virbac. 54p.	830.1600/Description of materials used to produce the product	Pass (14-Aug-2012)
48896301		Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/t04/t6/t1/OCR. Unpublished study prepared by Virbac. 54p.	830.1620/Description of production process	Pass (14-Aug-2012)
48896301		Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/t04/t6/t1/OCR. Unpublished study prepared by Virbac. 54p.	830.1650/Description of formulation process	Pass (14-Aug-2012)
48896301		Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/t04/t6/t1/OCR. Unpublished study prepared by Virbac. 54p.	830.1670/Discussion of formation of impurities	Pass (14-Aug-2012)
48896301		Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/t04/t6/t1/OCR. Unpublished study prepared by Virbac. 54p.	830.1750/Certified limits	Pass (14-Aug-2012)
48896302		Schoop, T. (2012) 104.16: Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxyfen in Five Batches by Validated Methods: Final Report. Project Number: D42226/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 79p.	830.1700/Preliminary analysis	Pass (14-Aug-2012)
48896302		Schoop, T. (2012) 104.16: Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxyfen in Five Batches by Validated Methods: Final Report. Project Number: D42226/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 79p.	830.1800/Enforcement analytical method	Pass (14-Aug-2012)
48896303		Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D42327/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 24p.	830.6302/Color	Pass (14-Aug-2012)
48896303		Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D42327/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 24p.	830.6303/Physical state	Pass (14-Aug-2012)
48896303		Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D42327/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 24p.	830.6304/Odor	Pass (14-Aug-2012)
48896304		Schoop, T. (2012) 104.16: Determination of Oxidation/Reduction: Chemical Incompatibility: Final Report. Project Number: D42305/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 33p.	830.6314/Oxidizing or reducing action	Pass (14-Aug-2012)
48896305		Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "Flash Point": Final Report. Project Number: D42316/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 29p.	830.6315/Flammability	Pass (14-Aug-2012)
48896306		Kuhne, M. (2011) 104.16: "Determination of the Physico-Chemical Property "Viscosity". Project Number: D42272/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 33p.	830.7100/Viscosity	Pass (14-Aug-2012)
48896307		Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "pH": Final Report. Project Number: D42294/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 27p.	830.7000/pH	Pass (14-Aug-2012)

DP#: (407438)

*** Product and Data Package Ingredients ***

Decision#: (468313)

PC Code	CAS	Ingredient Name
129032	95737-68-1	Pyriproxyfen
129121	120068-37-3	Fipronil
109701	52645-53-1	Permethrin
109701	52645-53-1	Permethrin(44.8%)
129032	95737-68-1	Pyriproxyfen(1.8%)
129121	120068-37-3	Fipronil(6%)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

From: Kevin Sweeney, Senior Entomologist

Date: February 18, 2013

A handwritten signature in black ink, appearing to read "Kevin Sweeney".

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 407443

Decision no.: 468313

Submission no: 921393

Action code: R310

Product Name: Effitix TM Plus Topical Solution for Dogs

EPA Reg. No or File Symbol: 2382-ROE

Formulation Type: RTU spot-on

Ingredients statement from the label with PC codes included: 6.0% fipronil (pc code: 129121) 44.8% permethrin (pc code: 109701) and 1.8% pyriproxyfen (pc code: 129032)

Application rate(s) of product: prescribed sized vials are applied. The number of vials applied to an animal is dependent upon animal weight.

Use pattern: dog spot-on products

OCSPP Guidelines: 810.3300

I. Action Requested: Review cited studies and new product label.

II. Background: Registrant cited data and submitted one MRID that summarizes the cited efficacy data. The label for this product is the same as for EPA Reg. No. 2382-187, Effitix Topical Solution for Dogs, which contains 6.0% fipronil and 44.8% permethrin - the same level of adulticides found in the pending product. The insect growth regulator (IGR) the pyriproxyfen at a concentration of 1.8% has been added to the pending product to effect flea development. The new directions and marketing claims are based on the activity of this IGR against fleas.

III. Study Reviews:

MRID 48896314 Summary of Efficacy Data for Effitix Plus Topical Solution for Dogs.

This volume summarizes the finding and data in the following studies:

Virbac data: 48510701, 48467122, 48467123, 48467124, 48467125, 48467126, 48446127, 48446128, 48467129

Fipronil efficacy data:

Merial: 43212114, 43212115, 43212116, 43212119, 43212120, 43212121, 43212122, 43444901, 435777701, 43577712, 43577713, 43951701, 44088901, 44942011, 44942106, 45618501, 45620502, 45620503, 45628104, 45628105, 45866901, 43577712, 43121114, 43121115, 43121117, 43121122, 43121118, 45620504, 45620505, 45620506, 43444901, 43577701, 43951701, 45612701, 45620503, 45866901, 45620501, 45628102, 45628103, 45628201, 45866902, 46019202, 46019201

Coopers' Animal Health: 41038802, 41038803

Hartz Mountain Corporation: 431372202, 431372203, 43111607

Ecto Development Corporation: 43396409, 43396410, 41683903, 43396409, 43396410

Wellmark: 46006002,

Bayer: 46978901

Permethrin efficacy data:

Cooper's Animal Health: 42256901

Ecto Development Corporation: 43396409 and 43396410

Pyriproxyfen efficacy data:

Virbac AH, Inc.: 44900904 and 45020601

IV. ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

1. The label is acceptable provided the following marketing claims are removed:

- "Prevents all immature flea stages in the dog's environment from developing."
- "Sterilizes and kills adult fleas.".



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

January 11, 2013

MEMORANDUM: Acute Toxicity DERs for 2382-ROE

Subject: Name of Pesticide Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS
EPA Reg. No. /File Symbol: 2382-ROE
DP Barcode: DP 407435
Decision No.: 468313
Action Code: R310
PC Code: 109701 (Permethrin: 44.6%)
129121 (Fipronil: 6.0%)
129032 (Pyriproxyfen: 1.8%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Jan - 11 - 2013
M. Hashmi

To: Driss Benmhend/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: VIRBAC AH, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	6.0%
109701 Permethrin	44.8%
129032 Pyriproxyfen	1.8%
<u>Other Ingredients:</u>	<u>47.4%</u>
TOTAL	100.0%

ACTION REQUESTED: "Virbac has requested the registration of this fipronil/permethrin/nylar product... This is the acute toxicology package. All of the studies referenced are in Documentum, so there are no hard copies to send with this bean."

COMMENTS AND RECOMMENDATIONS:

1. The five acute toxicity studies (MRIDs 48896309 through 48896313) have been classified as acceptable, and TRB concludes that a waiver of the inhalation study (with assignment to toxicity category IV by this exposure route) is appropriate. These five studies and the inhalation study waiver satisfy the acute toxicity data requirements for the registration of EPA File Symbol 2382-ROE.
2. Based on the results of the five studies and inhalation study waiver, the following is the acute toxicity profile of EPA File Symbol 2382-ROE:

Acute oral toxicity	III	Acceptable	MRID 48896309
Acute dermal toxicity	III	Acceptable	MRID 48896310
Acute inhalation toxicity	IV	Waived	n/a
Primary Eye irritation	III	Acceptable	MRID 48896311
Primary Dermal Irritation	IV	Acceptable	MRID 48896312
Dermal Sensitization	Negative	Acceptable	MRID 48896313

3. Based on the acute toxicity profile as well as information from the Confidential Statement of Formula and the uses indicated on the proposed label, the following is the precautionary and first aid labeling for 2382-ROE as obtained from the TRB Label Review System:

PRODUCT ID #: 002382-00192

PRODUCT NAME: EFFITEX® PLUS TOPICAL SOLUTION FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate].

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

4. This memorandum addresses only the acute toxicity data requirements for 2382-ROE; the companion animal safety data requirements for this product will be addressed in a separate action.
5. The TRB Chemistry Team should review and accept the CSF dated July 12, 2012.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager (EPA): 10

Date: January 11, 2013

The following table is the Acute Toxicity Data Evaluation Record (DER) for the five studies and inhalation toxicity waiver request supporting the proposed product, File Symbol 2382-ROE:

1. DP BARCODE: 407435				
2. PC CODES: 109701 (Permethrin: 44.6%), 129121 (Fipronil: 6.0%), 129032 (Pyriproxyfen: 1.8%)				
3. CURRENT DATE: January 11, 2013				
Test material: test item 104.16, batch no. NDE 11257-2, a clear yellowish solution containing 6.6% w/v fipronil, 2.0% w/v pyriproxyfen and 50.4% w/v permethrin. Density: 1.114 g/cm ³ .				
Study/Species/Lab Study #/Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Harlan Laboratories, 4452 Itingen, Switzerland / Harlan Laboratories Study D42171 / Jan. 13, 2012 / OCSPP 870.1100; OECD 425	48896309	LD ₅₀ (F) = 2000 mg/kg [1/3 dosed at 2000 mg/kg died]; Mortality: 550 mg/kg: 0/1; 2000 mg/kg: 1/3 (total of 4 animals dosed). Signs of toxicity: 550 mg/kg: dragging of limbs, straub phenomenon (tail rigid; erected across back in an S-shaped curve), hunched posture on days 1-3, tachypnea on day 1, muscle twitching, decreased activity and/or ruffled fur on days 2-3; similar effects were observed in the 2000 mg/kg animals. Rat that died did so on day 7. Gross necropsy: decedent had discoloured and dark red lungs; survivors were normal.	III	A
Acute dermal toxicity / rat Harlan Laboratories, 4452 Itingen, Switzerland / Harlan Laboratories Study D42182 / Jan. 13, 2012 / OCSPP 870.1200; OECD 402	48896310	LD ₅₀ > 2000 mg/kg (both sexes). No deaths. 1M & 1F vocalized after being touched on day 1; otherwise no abnormal systemic effects. 1M & 1F showed slight erythema on day 2. No abnormal findings at necropsy. 1M & 2F had slight weight losses day 1-8; all had wt gains day 1-15.	III	A
Acute inhalation toxicity / rat Waiver Request / OCSPP 870.1300; OECD 403	n/a	Vapor pressures of all 3 actives very low; maximum volume that could be administered to a dog at one time would be 6 mL.	IV	W

Primary eye irritation / rabbit Harlan Laboratories, 4452 Itingen, Switzerland / Harlan Laboratories Study D42193 / Jan. 16, 2012 / OCSPP 870.2400; OECD 405	48896311	At 1 & 24 hrs 1/3 eyes was positive for conjunctival redness (score of 2). None of the eyes was positive at 48 hrs or subsequently. MMTS = 6.67 at 1 hr.	III	A
Primary dermal irritation / rabbit / Harlan Laboratories, 4452 Itingen, Switzerland / Harlan Laboratories Study D42204 / Jan. 13, 2012/ OCSPP 870.2500; OECD 404	48896312	All sites scored 2 for erythema at 1 hr., and one site also scored 1 for edema. At 24 hrs all sites scored 1 for erythema and one site also scored 1 for edema. At 48 hrs one site scored 1 for erythema; at 72 hrs all scores were zero. PII = 1.00; mean irritation score at 72 hrs = 0.00.	IV	A
Dermal sensitization (Buehler)/ guinea pig / Harlan Laboratories, 4452 Itingen, Switzerland / Harlan Laboratories Study D42215 / March 21, 2012 / OCSPP 870.2600; OECD 429	48896313	A concentration of 100% was used for induction and 15% in diethylene glycol monomethyl ether was used for challenge.	Non sen- si- tizer	A

**Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap
n/a = "not applicable"**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

January 15, 2013

MEMORANDUM: Companion Animal Study Citations for 2382-ROE

Subject: Name of Pesticide Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS
EPA Reg. No. /File Symbol: 2382-ROE
DP Barcode: DP 407441
Decision No.: 468313
Action Code: R310
PC Code: 109701 (Permethrin: 44.6%)
129121 (Fipronil: 6.0%)
129032 (Pyriproxyfen: 1.8%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Jan - 15 - 2013
T.L. TOXICOLOGY

To: Driss Benmhend/Richard Gebken RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: VIRBAC AH, INC.

FORMULATION FROM LABEL:


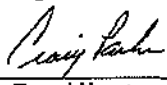
<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	6.0%
109701 Permethrin	44.8%
129032 Pyriproxyfen	1.8%
<u>Other Ingredients:</u>	<u>47.4%</u>
TOTAL	100.0%

ACTION REQUESTED: "Virbac has requested the registration of this fipronil/permethrin/nylar product. I'm requesting an expedited review... This is the Companion Animal Safety study. The minimum size for the dog was not provided on the label..."

COMMENTS AND RECOMMENDATIONS:

1. This package includes a listing of 29 previously submitted companion animal safety studies. Copies of the data matrix, proposed label and other documents are available from Documentum.
2. Virbac has previously registered (EPA Reg. No. 2382-187) a dog spot-on product with a label declaration of 6.01% Fipronil and 44.88% Permethrin as active ingredients. The additional active in 2382-ROE, Pyriproxyfen (or Nylar), has been demonstrated to have a very low toxicity to dogs, as shown in a 52-week capsule feeding study (MRID 42178309, included in the data matrix citations for 2382-ROE). The companion animal safety studies that were conducted on and/or used to support 2382-187 can also be used to support 2382-ROE, and can also be used by the Agency to set dosage levels. The proposed dosage rates for 2382-ROE are the same as those given on the last accepted (August 28, 2012) label for 2382-187. ✓
3. In a TRB review dated October 13, 2011 it was concluded that in a study in adult beagles (MRID 48467117) the margin of safety in 10- to 20-kg adult beagle dogs administered 104.05 [End-use Product: Effitix™ Topical Solution for Dogs] is at least 5x the recommended dose (2.0 mL/dog). This companion animal safety study in dogs was classified as **Acceptable/Guideline**.

However, there were two companion animal safety studies (MRIDs 48467118 and 48487302) with 8 week old beagle puppies in which severe adverse effects were seen at the 5X level (5.0 mL/puppy). Both of these studies were classified as **Unacceptable/Guideline** because an **adequate margin of safety was not demonstrated**. However, no adverse effects were observed at the 3X level (3.0 mL/puppy).
4. EPA Reg. 2382-187 was registered for use on dogs 12 weeks of age and older with a minimum dosage rate of 1.0 mL for dogs weighing less than 22.9 lbs. The registrant then proposed a new dosage rate of 0.5 mL for application to puppies to puppies 8 weeks of age or older and small dogs weighing between 4 and 10.9 lbs. This was accepted (because no adverse effects had been observed at the 3.0 mL/puppy dose in MRID 48467118) in a TRB memorandum dated August 13, 2012. The maximum dosage rate of 0.5 mL to a 4-lb dog is equivalent to 0.28 mL/kg.
5. Virbac subsequently submitted a study (MRID 48951001, not included in the list of studies cited by the registrant for 2382-ROE) on 10-week old beagle puppies as 6(a)(2) data. The adverse effects (including uncontrollable seizures which resulted in the euthanasia of one puppy) that occurred demonstrated that a dosage rate of 1.0 mL/puppy has a less than adequate (5X) margin of safety. The puppy that was euthanized was a male weighing 4.08 kg that received 5.0 mL, equivalent to 1.23 mL/kg; which when divided by 5 gives 0.245 mL/kg. In a review dated December 17, 2012 TRB recommended resetting the minimum weight to 5 lbs (=2.27 kg) which would result in a maximum 1X dosage rate of 0.22 mL/kg.
6. The cited companion animal safety studies adequately support the proposed uses for 2382-ROE, except **the label dosage rates should be revised to specify 5 lbs as the minimum weight rather than 4 lbs.**

 United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number Virbac AH, Inc./ 2382- xxx		2. EPA Product Manager Richard Gebken	
4. Company/Product (Name) EFFITIX™ PLUS Topical Solution for Dogs		3. Proposed Classification PM # t0 <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Virbac AH, Inc. P.O. Box 162059 Fort Worth, TX 76161 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment – Explain below		<input type="checkbox"/> Final printed labels in response to	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		Agency letter dated _____	
<input type="checkbox"/> Notification – Explain below		<input type="checkbox"/> "Me Too" Application	
		<input checked="" type="checkbox"/> Other – Explain below	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)			
Application for EFFITIX PLUS new product registration. PRIA Category R310. Please refer to attached letter.			
Section III			
1. Material This Product Will be Packaged in:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic, PETE <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
*Certification must be submitted		If "Yes" Unit Packaging wgt. 0.5	No. per container 1,3,6,36
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1, 3, 6 ml tubes	5. Location of label directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section IV			
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Craig Parks, MS, DVM		Title Vice President of Research and Development, Virbac AH, Inc.	Telephone No. (Include Area Code) 682-647-3576
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <div style="text-align: center;">[Stamped]</div>
2. Signature 		3. Title Vice President of Research and Development, Virbac AH, Inc.	
4. Typed Name Craig Parks, MS, DVM		5. Date August 3, 2012	



July 24, 2012

U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197

RE: Check for 2012 PRIA Fees; Virbac AH, Inc. (EPA Co. Number 2382)

Dear Sir or Madam:


Please find enclosed a check numbered **1016276** made out to the Environmental Protection Agency (EPA) in the amount of \$4,807.00. This check fulfills the financial obligations in support of an animal health pesticide, to be registered under the company Virbac AH, Inc. (EPA Company Number 2382). Also attached for reference are copies of the EPA Form 8570-1 with information on the registration of the with EPA.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Craig Parks". The signature is fluid and cursive.

Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement <i>(40 CFR 152.85)</i>		
Applicant's Name and Address Virbac Animal Health P. O. Box 162059 Ft. Worth, TX 76137	EPA File Symbol/Registration Number 2382-NEW Product Name EFFITIX™ PLUS Topical Solution for Dogs Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012	
As an authorized representative of the applicant for registration of the product identified above, I certify that:		
(1) This product contains the following active ingredient(s): permethrin		
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.		
(3) Indicate by checking (A) or (B) below which paragraph applies:		
<input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)		
OR		
<input type="checkbox"/> (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF		
(4) The following active ingredients in this product qualify for the formulator's exemption		
Source		
Active Ingredient	Product Name	Registration Number
Permethrin	[REDACTED]	[REDACTED]
Pyriproxyfen	[REDACTED]	[REDACTED]
Signature 	Name and Title Vice President, Research & Development	Date August 3, 2012

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
Yellow - Applicant copy

Virbac Effitix Plus
8/2/12

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac Animal Health, Inc. (EPA Company Number 2382)
P.O. Box 162059
Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use product named EFFITIX™ Plus Topical Solution for Dogs.

SUBMITTAL DATE:

August 2, 2012

Volume	Study Name (Lab Reference Number)	MRID
TRANSMITTAL DOCUMENT		48896300
✓ 1	Product Specific Chemistry For Effitix™ Plus Topical Solution for Dogs	48896301
✓ 2	Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxifen in Five Batches by Validated Methods	48896302
✓ 3	Determination of the physic-Chemical Property Appearance (Color, Physical State, and Odor) (D42327)	48896303
✓ 4	Determination of Oxidation/reduction: Chemical Incompatibility (D42305)	48896304
✓ 5	Determination of the Physico-Chemical Property "Flash Point" (D42316)	48896305
✓ 6	Determination of the Physico-Chemical Property Viscosity (D42272)	48896306
✓ 7	Determination of the Physico-Chemical Property pH (D42294)	48896307
✓ 8	Determination of the Physico-Chemical Property Relative Density (D42283)	48896308
✓ 9	Acute oral toxicity (D42171)	48896309
10	Acute dermal toxicity (D42182)	48896310
11	Primary eye irritation (D42193)	48896311
12	Primary dermal irritation (D42202)	48896312
13	Dermal sensitization (D42215)	48896313
14	Summary of Efficacy Data For Effitix™ Plus Topical Solution for Dogs	48896314
15	Summary of Companion Animal Safety Data For Effitix™ Plus Topical Solution for Dogs	48896315



August 2, 2012

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: EFFITIX™ PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);
New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382) is hereby submitting an application to register the spot-on pesticide product EFFITIX™ PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil at 6.0% w/w, permethrin at 44.8%, and pyriproxyfen at 1.8 % w/w and is intended to control fleas, ticks, mosquitoes, and other pests in dogs only.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Virbac is issuing Offer to Pay letters to the submitters of data not owned by Virbac and cited in this application that were originally submitted to EPA within the past 15 years.

Below is a list of the components included with this application:

1. Cover Letter;
2. Transmittal Document;
3. Application for Pesticide Form 8570-1 for EFFITIX™ PLUS Topical Solution For Dogs;
4. Confidential Statement of Formula for EFFITIX™ PLUS Topical Solution for Dogs;
5. Data Matrix Form 8570-4 for EFFITIX™ PLUS Topical Solution for Dogs;
6. Certification of Data Citation Form 8570-34 For EFFITIX™ PLUS Topical Solution For Dogs;
7. Proposed Use Directions for EFFITIX™ Topical Solution for Dogs - 5 copies;
8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
10. Letter of Self-certification of Child-Resistant Packaging;
11. Copy of PRIA Check for category R-310 (\$4807).

Child-Resistant Packaging Testing & Data

EFFITIX™ PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators that have been previously reviewed and approved by EPA as Child Resistant under the registration of EFFITIX™ Topical Solution for Dogs, (EPA Reg. No. 2382-187) and EFFIPRO Topical Solution For Cats (2382-186). Included with this submission is an updated Data Matrix citing all previously submitted data supporting CRP certification of the proposed presentations of EFFITIX PLUS. In addition, an updated CRP certification letter has been provided.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this new product application. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,



Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.

Virbac Effitix Plus
8/2/12

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac Animal Health, Inc. (EPA Company Number 2382)
P.O. Box 162059
Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use product named EFFITIX™ Plus Topical Solution for Dogs.

SUBMITTAL DATE:

August 2, 2012

Volume	Study Name (Lab Reference Number)	MRID
TRANSMITTAL DOCUMENT		48896300
1	Product Specific Chemistry For Effitix™ Plus Topical Solution for Dogs	48896301
2	Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxifen in Five Batches by Validated Methods	48896302
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4	Determination of Oxidation/reduction: Chemnical Incompatability (D42305)	48896304
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7	Determination of the Physico-Chemical Property pH (D42294)	48896307
8	Determination of the Physico-Chemical Property Relative Density (D42283)	48896308
9	Acute oral toxicity (D42171)	48896309
10	Acute dermal toxicity (D42182)	48896310
11	Primary eye irritation (D42193)	48896311
12	Primary dermal irritation (D42202)	48896312
13	Dermal sensitization (D42215)	48896313
14	Summary of Efficacy Data For Effitix™ Plus Topical Solution for Dogs	48896314
15	Summary of Companion Animal Safety Data For Effitix™ Plus Topical Solution for Dogs	48896315

Waiver Request

Registrant: Virbac Animal Health, Inc.

Acute Inhalation Study (OPPTS 830.1300).

Brandname: Effitix™ PLUS Topical Solution for Dogs.

The Effitix PLUS Topical Solution for Dogs product is composed of 6.0% w/w of the active ingredient fipronil, 44.8% w/w of the active ingredient permethrin and 1.8% w/w of the active ingredient pyriproxifen. This product is packaged in single use non-refillable applicators that are intended for one time only spot-on applications to dogs.

The potential human inhalation exposure to this product is expected to be negligible. Only very small amounts of product are applied per application, depending the weight of the animal. Based on packaging considerations described in the proposed product labeling, the maximum volume of Effitix PLUS Topical Solution that can be administered at one time to a pet using the largest available applicator size is approximately 6.0 ml. This application volume represents the worst case because it is the dose that is recommended only for use on dogs weighing more than 89 pounds. Therefore, according to the proposed label, a great deal of anticipated product use will occur at much lower volumes on smaller dogs.

Furthermore, the measured vapor pressure of all three active ingredients fipronil permethrin, and pyriproxifen are extremely low (2.8×10^{-9} mm Hg @ 25°C , 2.18×10^{-8} mm Hg @ 25°C , and 1.0×10^{-7} mm Hg @ 20°C , respectively) indicating that all three active ingredients are essentially non-volatile and are therefore not expected to vaporize from the skin of the treated animal following application. The active ingredients will therefore not be available for inhalation after application according to label directions. Finally, the method of applying the liquid product directly to the pet creates no particulates, aerosols, or other respirable matter. Therefore, based on the criteria provided by the Agency in 40 CFR 158.500, footnote 4 under the Toxicology Data Requirements, a waiver of the acute inhalation study for these products is appropriate.



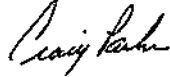
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: July 31, 2012				EPA Reg. No./File Symbol 2382- TBA		Page 1 of 11
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161				Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Permethrin, Pyriproxifen						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
Product Chemistry 830 Series Group A Test Guidelines						
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN		
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN		
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN		
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN		
830.1670	Description of Formation of Impurities	New Submission	Virbac AH, Inc.	OWN		
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN		
830.1700, 830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN		
Product Chemistry 830 Series Group B Test Guidelines						
830.6302	Color	New Submission	Virbac AH, Inc.	OWN		
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN		
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN		
830.6313	Metal Stability		Virbac AH, Inc.	NR		
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN		
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN		
830.6316	Explosibility		Virbac AH, Inc.	NR		
830.6317	Storage stability	To Be Conducted	Virbac AH, Inc.	OWN		
Signature 			Name and Title Craig Parks Vice President, Research & Development			Date July 31, 2012

EPA Form 8170-11 (9-97) Electronic and Paper Versions Available. Submit only Paper version.

Agency Internal Use Copy



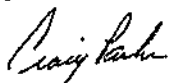
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: July 31, 2012		EPA Reg. No./File Symbol 2382- TBA		Page 2 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry 830 Series Group B Test Guidelines					
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To Be Conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle Size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver requested	Virbac AH, Inc.	OWN	waiver
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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DATA MATRIX

Date: July 31, 2012			EPA Reg. No./File Symbol 2382- TBA		Page 3 of 11
Applicant's/Registrant's Name & Address Virbac AH, Inc 110 Box 162059 Fort Worth TX 76161			Product: EFFITIX™ TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
870.7200	Companion Animal safety 14 d pup study-1	48487302	Virbac AH, Inc	OWN	
870.7200	Companion Animal safety-Beagle Dog	48467117	Virbac AH, Inc.	OWN	
870.7200	Companion Animal safety-14 d pup study-2	48467118	Virbac AH, Inc.	OWN	
870.7200	Companion Animal safety Summary	48467119	Virbac AH, Inc	OWN	
870.7200	Companion Animal safety - Method Valid.	48467120	Virbac AH, Inc	OWN	
810.3300	Product Performance - Flea onset of Action	48510701	Virbac AH, Inc	OWN	
810.3300	Product Performance - Rhipicephalus action	48467122	Virbac AH, Inc.	OWN	
810.3300	Product Performance - D. variabilis action	48467123	Virbac AH, Inc	OWN	
810.3300	Product Performance - Shampoo study	48467124	Virbac AH, Inc	OWN	
810.3300	Product Performance - Amblyoma efficacy	48467125	Virbac AH, Inc	OWN	
810.3300	Product Performance - Ixodes efficacy	48467126	Virbac AH, Inc.	OWN	
810.3300	Product Performance - Mosquito efficacy	48467127	Virbac AH, Inc	OWN	
810.3300	Product Performance - Tick repellency	48467128	Virbac AH, Inc	OWN	
810.3300	Product Performance - Efficacy Summary	48467129	Virbac AH, Inc.	OWN	
Efficacy and Safety Data- Fipronil					
870.7200	Companion Animal safety	43444905	Merial	OLD	
870.7200	Companion Animal safety	43577711	Merial	OLD	
870.7200	Companion Animal safety	43863802	Merial	OLD	
870.7200	Companion Animal safety	43121110	Merial	OLD	
870.7200	Companion Animal safety	43121111	Merial	OLD	
870.7200	Companion Animal safety	45612702	Merial	PAY	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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DATA MATRIX

Date: July 31, 2012			EPA Reg. No./File Symbol 2382-TBA		Page 4 of 11
Applicant's/Registrant's Name & Address Virbac All, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MIRID Number	Submitter	Status	Note
Efficacy and safety data -Fipronil					
810.3300	Product Performance - Efficacy-flea	43121114	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121115	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121116	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121119	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121120	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121121	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121122	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43444901	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43577701	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43577712	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43577713	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43951701	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	44088901	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	44942011	Merial	PAY	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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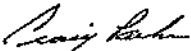
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DATA MATRIX

Date July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 5 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient Fipronil, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and safety data -Fipronil					
810.3300	Product Performance - Efficacy-flea	44942106	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45618501	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45620502	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45620503	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45628104	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45628105	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45866901	Merial	PAY	
810.3300	Product Performance - Efficacy-lick	43577712	Merial	OLD	
810.3300	Product Performance - Efficacy-lick	43121114	Merial	OLD	
810.3300	Product Performance - Efficacy-lick	43121115	Merial	OLD	
810.3300	Product Performance - Efficacy-lick	43121117	Merial	OLD	
810.3300	Product Performance - Efficacy-lick	43121122	Merial	OLD	
810.3300	Product Performance- Efficacy Bathing	43121118	Merial	OLD	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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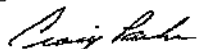
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DATA MATRIX

Date: July 31, 2012			EPA Reg. No./File Symbol 2382-TBA		Page 6 of 11
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and safety data -Fipronil					
810.3300	Product Performance -- Efficacy-Mange	45620504	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mange	45620505	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mange	45620506	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mites	43444901	Merial	OLD	
810.3300	Product Performance -- Efficacy-Mites	43577701	Merial	OLD	
810.3300	Product Performance -- Efficacy-Mites	43951701	Merial	OLD	
810.3300	Product Performance -- Efficacy-Mites	45612701	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mites	45620503	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mites	45866901	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45620501	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45628101	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45628102	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45628103	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45628201	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mosquito	45866902	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mosquito	46019202	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mosquito	46019201	Merial	PAY	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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DATA MATRIX

Date July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 7 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data- Permethrin					
870.7200	Companion Animal safety	41056906	Coopers Animal Health, Inc	OLD	
870.7200	Companion Animal safety	41953201	Coopers Animal Health, Inc.	OLD	
870.7200	Companion Animal safety	43137201	Hartz Mountain Corporation	OLD	
870.7200	Companion Animal safety	43447101	Hartz Mountain Corporation	OLD	
870.7200	Companion Animal safety	43396408	ECTO Development Corporation	OLD	
870.7200	Companion Animal safety	43612601	ECTO Development Corporation	OLD	
810.3300	Product Performance - Efficacy	41038802	Cooper's Animal Health	OLD	
810.3300	Product Performance - Efficacy	41038803	Cooper's Animal Health	OLD	
810.3300	Product Performance - Efficacy	43137202	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43137203	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	46006002	Wellmark	PUB	
810.3300	Product Performance - Efficacy	41683903	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43111607	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy-Biting Fly	46978901	Bayer Healthcare LLC	PAY	11-13-06
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012



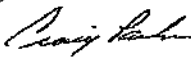
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DATA MATRIX

Date: July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 8 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data- Permethrin					
810.3300	Product Performance - Efficacy	42256901	Cooper's Animal Health, Inc.	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
Efficacy and Safety Data- Pyriproxifen					
870.7200	Companion Animal safety	43396408	Ecto Development Corporation	OLD	
870.7200	Companion Animal Safety	43612601	Ecto Development Corporation	OLD	
870.7200	Companion Animal Safety	44900902	Virbac AH, Inc.	OWN	
870.7200	Companion Animal Safety	44900903	Virbac AH, Inc.	OWN	
870.7200	Companion Animal Safety	42178309	Sumitomo Chemical Company, Ltd.	OLD	
810.3300	Product Performance - Efficacy	44900904	Virbac AH, Inc.	OWN	
810.3300	Product Performance - Efficacy	45020601	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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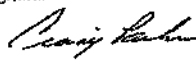
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DATA MATRIX

Date: July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 9 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 1 applicator tube test as a Poison Prevention Package for Virbac SA	48467130	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467131	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 6 applicator tubes test as a Poison Prevention Package for Virbac SA	48467132	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbac	48467133	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 1 applicator tube test as a Poison Prevention Package for Virbac SA	48467134	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467135	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 6 applicator tubes test as a Poison Prevention Package for Virbac SA	48467136	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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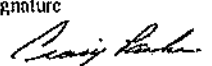
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DATA MATRIX

Date: July 12, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 10 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc P.O. Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbac SA	48467137	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 1 applicator tube test as a Poison Prevention Package for Virbac SA	48467138	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467139	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 6 applicator tubes test as a Poison Prevention Package for Virbac SA	48467140	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbac SA	48467141	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 1 applicator tube test as a Poison Prevention Package for Virbac SA	48467142	Virbac AH, Inc.	OWN	Vol 43
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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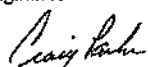
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DATA MATRIX

Date: July 31, 2012			EPA Reg. No./File Symbol 2382-TBA		Page 11 of 11
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467143	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 6 applicator tubes test as a Poison Prevention Package for Virbac SA	48467144	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbac SA	48467145	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095215	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicator tubes test for Child-Resistant Effectiveness	48095216	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicator tubes test for Child-Resistant Effectiveness	48095217	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095218	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicator tubes test for Senior-Use Effectiveness	48095219	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicator tubes test for Senior-Use Effectiveness	48095220	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.50 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410018	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.50 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410019	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement <i>(40 CFR 152.85)</i>					
Applicant's Name and Address Virbac Animal Health P. O. Box 162059 Ft. Worth, TX 76137	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 100%;">EPA File Symbol/Registration Number 2382-NEW</td> </tr> <tr> <td>Product Name EFFITIX™ PLUS Topical Solution for Dogs</td> </tr> <tr> <td>Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012</td> </tr> </table>		EPA File Symbol/Registration Number 2382-NEW	Product Name EFFITIX™ PLUS Topical Solution for Dogs	Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012
EPA File Symbol/Registration Number 2382-NEW					
Product Name EFFITIX™ PLUS Topical Solution for Dogs					
Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012					
As an authorized representative of the applicant for registration of the product identified above, I certify that:					
(1) This product contains the following active ingredient(s): permethrin					
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.					
(3) Indicate by checking (A) or (B) below which paragraph applies:					
<input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)					
OR					
<input type="checkbox"/> (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF					
(4) The following active ingredients in this product qualify for the formulator's exemption					
Source					
Active Ingredient	Product Name	Registration Number			
Permethrin	[REDACTED]	[REDACTED]			
Pyriproxyfen	[REDACTED]	[REDACTED]			
Signature 	Name and Title Vice President, Research & Development	Date August 3, 2012			

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
Yellow - Applicant copy

Virbac Effitix Plus
8/2/12

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac Animal Health, Inc. (EPA Company Number 2382)
P.O. Box 162059
Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use product named EFFITIX™ Plus Topical Solution for Dogs.

SUBMITTAL DATE:

August 2, 2012

Volume	Study Name (Lab Reference Number)	MRID
TRANSMITTAL DOCUMENT		48896300
1	Product Specific Chemistry For Effitix™ Plus Topical Solution for Dogs	48896301
2	Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxifen in Five Batches by Validated Methods	48896302
3	Determination of the physic-Chemical Property Appearance (Color, Physical State, and Odor) (D42327)	48896303
4	Determination of Oxidation/reduction: Chemical Incompatability (D42305)	48896304
5	Determination of the Physico-Chemical Property "Flash Point" (D42316)	48896305
6	Determination of the Physico-Chemical Property Viscosity (D42272)	48896306
7	Determination of the Physico-Chemical Property pH (D42294)	48896307
8	Determination of the Physico-Chemical Property Relative Density (D42283)	48896308
9	Acute oral toxicity (D42171)	48896309
10	Acute dermal toxicity (D42182)	48896310
11	Primary eye irritation (D42193)	48896311
12	Primary dermal irritation (D42202)	48896312
13	Dermal sensitization (D42215)	48896313
14	Summary of Efficacy Data For Effitix™ Plus Topical Solution for Dogs	48896314
15	Summary of Companion Animal Safety Data For Effitix™ Plus Topical Solution for Dogs	48896315

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx
Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil.....	6.0%
Permethrin*	44.8%
Pyriproxyfen.....	1.8%

OTHER INGREDIENTS: 47.4%

TOTAL: 100.0%

* cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING :	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.	

Inside flap (single presentation insert only)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs and puppies under 8 weeks of age. Do not spill tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

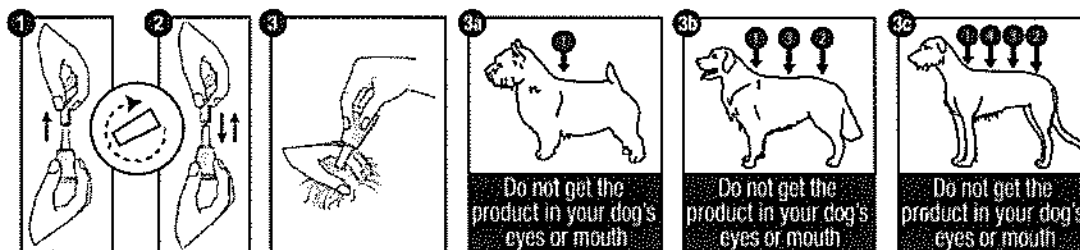
Do not apply more often than once a [per] month (every 30 days).

For use on DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs and puppies 8 weeks old or older weighing 4 to 10.9 lbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIX™ Plus Topical Solution for Dogs is not applied superficially on dog's hair.



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing] and lice infestations can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.

Fleas: EFFITIX™ Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for [up to] three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for [up to] a month. Apply monthly where lice control is consistently needed.

Mites: EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of [sarcoptic mange]/[mite infestations] that may cause sarcoptic mange.

Biting flies and Mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for up to 4 weeks [a (one) month]. Kills mosquitoes for up to four weeks [a (one) month].

Notes: Wait at least 30 days before re-application of EFFITIX™ Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs 11 to 22.9 lbs (0.034 fl oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.068 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1 mL, 2 mL, 4 mL or 6 mL)/ 0.017 fl oz, (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (of solution).

[Detachable] calendar (monthly application) reminder stickers (with illustration of dog or puppy)

Back Panel (single presentation on side panel)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-FRA-1

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH TX 76161
1-800-338-3659

Made in France
EFFITIX™ is a trademark of Virbac S.A.
Questions or comments? Call: 1-800-338-3659.

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application
See package insert for directions for use and storage and disposal
See package insert for frequency of application and storage and disposal
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs ONLY
Use ONLY on dogs
See inside flap for directions for use

Text for Foil of Blister package

Virbac

EFFITIX™ Plus Topical Solution For Dogs

Only for use on dogs (4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)

Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

DO NOT USE ON CATS

CAT PROHIBITION ICON

Text for Applicator Tube

Virbac

EFFITIX™ Plus

Topical Solution For Dogs

Only for use on dogs

(4 to 10.9 lbs, 11 to 22.9 lbs 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/

(0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL))

Contains fipronil (6.0%), permethrin (44.8%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

DO NOT USE ON CATS

EPA Reg. No. 2382-xxx

CAT PROHIBITION ICON

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] (lice, aids in the control of sarcoptic mites, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] (lice, aids in the control of mites that may cause sarcoptic mange, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs (8 weeks old or older) and 4 to 10.9 lbs [0.17 fl oz] (0.5 mL), small dogs 11 to 22.9 lbs [0.034 fl oz] (1.0 mL), medium dogs 23-44.9 lbs [0.068 fl oz] (2.0 mL), large dogs 45-88.9 lbs [0.135 fl oz] (4.0 mL), and extra large dogs 89-132 lbs [0.203 fl oz] (6.0 mL).
- EFFITIX™ Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel [against] biting flies, and repel and kill mosquitoes.
- Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, [and lice] infestations

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Helps to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

[Fleas]

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX™ Plus Topical Solution for Dogs
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills [adult] fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen [IGR]* to break [the] flea life cycle
*insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis, [tularemia] [and tapeworm infestations]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [*Dipylidium caninum*]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills [adult] fleas [within 6 hours] that may cause Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD [Flea Allergy Dermatitis]
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to [90 days] [3 months])
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] however if your dog is susceptible to Flea Allergy Dermatitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae
- EFFITIX™ Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 6 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides ongoing protection against fleas and the following diseases: bartonellosis, [tularemia] [and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)
- Treatment with EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea [prevention] [protection] year-round

[Ticks]

- Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for [up to] at least [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of *Brown dog ticks*, *American dog ticks*, *Lone Star ticks*, and *Deer ticks* (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including *Deer ticks* [that may transmit Lyme disease and anaplasmosis], *American dog ticks* [that may transmit Rocky Mountain Spotted Fever], *Brown dog ticks* [that may transmit ehrlichiosis], and *Lone Star ticks* [that may transmit hepatozoonosis] for up to one month [4 weeks]
- Kills ticks including *Deer ticks* [that may transmit Lyme disease and anaplasmosis], *American dog ticks* [that may transmit Rocky Mountain Spotted Fever], and *Brown dog ticks* [that may transmit ehrlichiosis] for up to one month [4 weeks].
- Kills *Brown dog ticks* (*Rhipicephalus* spp), *American dog ticks* (*Dermacentor variabilis*), *Deer ticks* [*Ixodes* spp] and *Lone Star ticks* [*Amblyomma americanum*] for up to one month [4 weeks].
- Kills *Lone Star ticks* (*Amblyomma americanum*) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks] [a (one) month]
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for [up to] 4 weeks [a (one) month]
- Repels and kills mosquitoes for up to four [4] weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [[Prevents blood-feeding by] [Kills and repels]] mosquitoes
- Repels biting flies
- Repels [[annoying][bothersome][nuisance]] biting flies
- Inhibits [[annoying][bothersome] [nuisance]] biting flies
- [[Prevents][inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos [*Culex* spp, *Ochlerotatus* spp, *Aedes* spp] which may vector heartworm [*Dirofilaria immitis*] for one month

[Lice and Mites]

- Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for a [one] month. Apply monthly where lice control is consistently needed.
- Mites: (EFFITIX™ Plus Topical Solution for Dogs) aids in [the] control of mites that may cause sarcoptic mange.
- Mites: (EFFITIX™ Plus Topical Solution for Dogs) aids in [the] control of sarcoptic mites
- EFFITIX™ Plus Topical Solution for Dogs aids in (the) control of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIX™ Plus Topical Solution for Dogs aids in (the) control of sarcoptic mange.
- Aids in [the] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- [Also] Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills [(biting) (chewing)] lice
- For control and prevention of [(biting) (chewing)] lice [infestations]
- Stops existing [(biting) (chewing)] lice infestations
- Prevents and controls [(biting) (chewing)] lice [infestations]
- Provides effective control of [(biting) (chewing)] lice [infestations]
- Kills [(biting) (chewing)] lice and prevents further infestations
- For control and prevention of [infestation][with] [(biting) (chewing)] lice

[Others]

- t (3, 6, 36) applicator(s) (tube[s]) 0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- t (3, 6, 36) applicator(s) (tube[s]) 0.017 fl oz (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- t (3, 6, 36) applicator(s) (tube[s]) 0.017 fl oz [0.5 mL], (0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL])
- t (3, 6, 36) applicator(s) (tube[s]) (each) containing 0.017 fl oz (0.5mL) (0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL])
- t (3, 6, 36) applicator(s) (tube[s])
- t (3, 6, 36) monthly dose(s) [application(s)]
- t (3, 6, 36) applicator(s) (tube[s]) 1 (3, 6, 36) month(ly) dose(s) [application(s)]
- DO NOT USE ON CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 11 to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs]
- Easy and convenient application [applications]
- Remains effective for a (one) month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month

- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-]infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply] spot-on [topical] application
- Fragrance [odor] free
- No noticeable odors
- Single application lasts 4 weeks [one month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]
- EFFITIXTM Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof [remains effective after bathing and swimming] for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [[for a month] [for one month] [for up to four weeks]]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package [applicator tubes]

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application
See package insert for directions for use and storage and disposal
See package insert for frequency of application and storage and disposal
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs ONLY
Use ONLY on dogs
See inside flap for directions for use

Text for Foil of Blister package

Virbac

EFFITIX™ Plus Topical Solution For Dogs

Only for use on dogs (4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)

Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

DO NOT USE ON CATS

CAT PROHIBITION ICON

Text for Applicator Tube

Virbac

EFFITIX™ Plus

Topical Solution For Dogs

Only for use on dogs

(4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/

(0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) [/ (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)]

Contains fipronil (6.0%), permethrin (44.8%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

DO NOT USE ON CATS

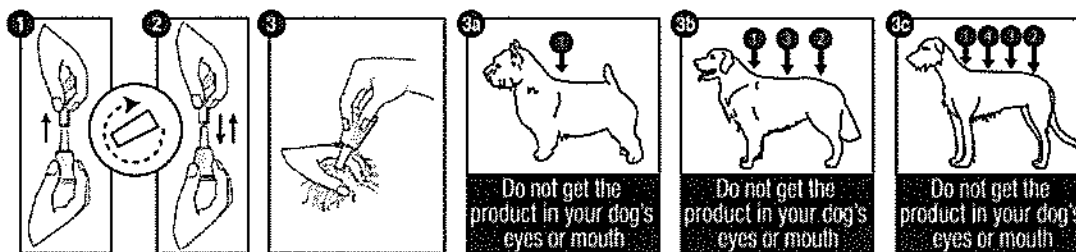
EPA Reg. No. 2382-xxx

CAT PROHIBITION ICON

MARKETING CLAIMS

[Multiple Infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of sarcoptic mites, and repels (and inhibits blood feeding by) biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of mites that may cause sarcoptic mange, and repels (and inhibits blood feeding by) biting flies and mosquitoes.
- For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 4 to 10.9 lbs (0.17 fl oz) [0.5 mL], small dogs 11 to 22.9 lbs [0.034 fl oz] [1.0 mL], medium dogs 23-44.9 lbs [0.068 fl oz] [2.0 mL], large dogs 45-88.9 lbs [0.135 fl oz] [4.0 mL], and extra large dogs 89-132 lbs [0.203 fl oz] [6.0 mL].
- EFFITIX™ Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel (against) biting flies, and repel and kill mosquitoes.
- Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, [and lice] infestations



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing] and lice infestations can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.

Fleas: EFFITIX™ Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for [up to] three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for [up to] a month. Apply monthly where lice control is consistently needed.

Mites: EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of [sarcoptic mange]/[mite infestations that may cause sarcoptic mange].

Biting flies and Mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for up to 4 weeks [a [one] month]. Kills mosquitoes for up to four weeks [a [one] month].

Notes: Wait at least 30 days before re-application of EFFITIX™ Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs 11 to 22.9 lbs (0.034 fl oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.068 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1mL, 2mL, 4mL or 6mL)/ 0.017 fl oz, (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (of solution).

[Detachable] calendar (monthly application) reminder stickers (with illustration of dog or puppy]

Back Panel (single presentation on side panel)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-FRA-1

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH TX 76161
1-800-338-3659

Made in France
EFFITIX™ is a trademark of Virbac S.A.
Questions or comments? Call: 1-800-338-3659.

Back Panel (single presentation on insert)

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.	

Inside flap (single presentation insert only)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labelling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs and puppies under 8 weeks of age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

Do not apply more often than once a [per] month [every 30 days].

For use on DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs and puppies 8 weeks old or older weighing 4 to 10.9 lbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIX™ Plus Topical Solution for Dogs is not applied superficially on dog's hair.

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx
Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil.....	6.0%
Permethrin*	44.8%
Pyriproxyfen.....	1.8%

OTHER INGREDIENTS: 47.4%

TOTAL: 100.0%

* cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Helps to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

[Fleas]

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX™ Plus Topical Solution for Dogs
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills [adult] fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen [IGR]* to break [the] flea life cycle
*insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis, [tularemia] [and tapeworm infestations]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [*Dipylidium caninum*]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills [adult] fleas [within 6 hours] that may cause Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD [Flea Allergy Dermatitis]
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to [90 days] [3 months]]
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] however if your dog is susceptible to Flea Allergy Dermatitis [FAD] it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae
- EFFITIX™ Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or if reinfestation is likely.
- Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides ongoing protection against fleas and the following diseases: bartonellosis, [tularemia] [and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents [Stops] re-infestations by killing adult fleas [before they lay eggs]
- Treatment with EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea [prevention] [protection] year-round

[Ticks]

- Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for [up to] [at least [one] month]. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], Brown dog ticks [that may transmit ehrlichiosis], and Lone Star ticks [that may transmit hepatozoonosis] for up to one month [4 weeks]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], and Brown dog ticks [that may transmit ehrlichiosis] for up to one month [4 weeks].
- Kills Brown dog ticks [*Rhipicephalus* spp], American dog ticks [*Dermacentor variabilis*], Deer ticks [*Ixodes* spp] and Lone Star ticks [*Amblyomma americanum*] for up to one month [4 weeks].
- Kills Lone Star ticks [*Amblyomma americanum*] for 4 weeks [for up to one month].
- Effective monthly application against ticks

[Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks] [a [one] month]
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for [up to] 4 weeks [a [one] month]
- Repels and kills mosquitoes for up to four [4] weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents [inhibits] blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [[Prevents blood-feeding by] [Kills and repels]] mosquitoes
- Repels biting flies
- Repels [[annoying][bothersome][nuisance]] biting flies
- Inhibits [[annoying][bothersome] [nuisance]] biting flies
- [[Prevents][inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos [*Culex* spp, *Ochlerotatus* spp, *Aedes* spp] which may vector heartworm [*Dirofilaria immitis*] for one month

[Lice and Mites]

- Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for a [one] month. Apply monthly where lice control is consistently needed.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs] aids in [the] control of mites that may cause sarcoptic mange.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs] aids in [the] control of sarcoptic mites
- EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of sarcoptic mange.
- Aids in [the] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- [Also] Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills [[biting] [chewing]] lice
- For control and prevention of [[biting] [chewing]] lice [infestations]
- Stops existing [[biting] [chewing]] lice infestations
- Prevents and controls [[biting] [chewing]] lice [infestations]
- Provides effective control of [[biting] [chewing]] lice [infestations]
- Kills [[biting] [chewing]] lice and prevents further infestations
- For control and prevention of [infestation][with] [[biting] [chewing]] lice

[Others]

- t (3, 6, 36) applicator(s) (tube(s)) 0.5 mL { 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL}
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.017 fl oz (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.017 fl oz [0.5 mL], [0.034 fl oz { 1.0 mL}, 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL]]
- 1 (3, 6, 36) applicator(s) (tube(s)) (each) containing 0.017 fl oz [0.5mL] { 0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL]}
- 1 (3, 6, 36) applicator(s) (tube(s))
- 1 (3, 6, 36) monthly dose(s) (application(s))
- t (3, 6, 36) applicator(s) (tube(s)) 1 (3, 6, 36) month(ly) dose(s) (application(s))
- DO NOT USE ON CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 11 to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs]
- Easy and convenient application [applications]
- Remains effective for a [one] month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, [biting, chewing] lice and biting flies is prevented for a (one) month

- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-]infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply] spot-on [topical] application
- Fragrance [odor] free
- No noticeable odors
- Single application lasts 4 weeks [one month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]
- EFFITIXTM Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof [remains effective after bathing and swimming] for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [(for a month) [for one month] [for up to four weeks]]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package [applicator tubes]

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx
Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil.....	6.0%
Permethrin*	44.8%
Pyriproxyfen.....	1.8%

OTHER INGREDIENTS:	47.4%
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TOTAL:	100.0%
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* cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING :	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>Have product container or label with you when calling a poison control center or doctor, or going for treatment.</p> <p>You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.</p>	

Inside flap (single presentation insert only)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labelling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs and puppies under 8 weeks of age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

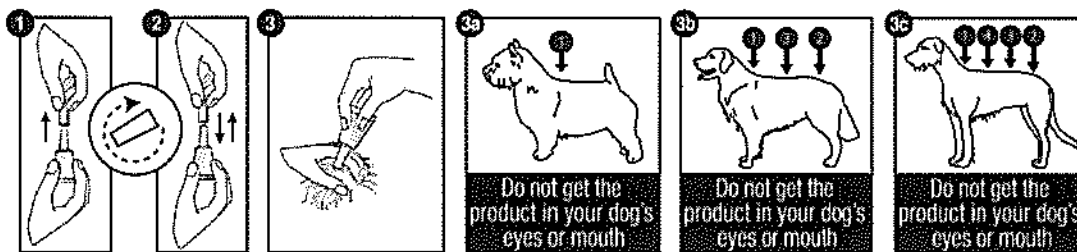
Do not apply more often than once a (per) month [every 30 days].

For use on DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs and puppies 8 weeks old or older weighing 4 to 10.9 lbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIXTM Plus Topical Solution for Dogs is not applied superficially on dog's hair.



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing] and lice infestations can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.

Fleas: EFFITIX™ Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for [up to] three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for [up to] a month. Apply monthly where lice control is consistently needed.

Mites: EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of [sarcoptic mange]/[mite infestations that may cause sarcoptic mange].

Biting flies and Mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for up to 4 weeks [a (one) month]. Kills mosquitoes for up to four weeks [a (one) month].

Notes: Wait at least 30 days before re-application of EFFITIX™ Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs 11 to 22.9 lbs (0.034 fl oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.068 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1mL, 2mL, 4mL or 6mL)/(0.017 fl oz, (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

Back Panel (single presentation on side panel)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-FRA-1

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH TX 76161
1-800-338-3659

Made in France
EFFITIX™ is a trademark of Virbac S.A.
Questions or comments? Call: 1-800-338-3659.

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application
See package insert for directions for use and storage and disposal
See package insert for frequency of application and storage and disposal
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs ONLY
Use ONLY on dogs
See inside flap for directions for use

Text for Foil of Blister package

Virbac

EFFITIX™ Plus Topical Solution For Dogs

Only for use on dogs (4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)

Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

DO NOT USE ON CATS

CAT PROHIBITION ICON

Text for Applicator Tube

Virbac

EFFITIX™ Plus

Topical Solution For Dogs

Only for use on dogs

(4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs) (

0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) / (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)]

Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

DO NOT USE ON CATS

EPA Reg. No. 2382-xxx

CAT PROHIBITION ICON

MARKETING CLAIMS

[Multiple Infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of sarcoptic mites, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of mites that may cause sarcoptic mange, and repels (and inhibits blood feeding by) biting flies and mosquitoes.
- For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 4 to 10.9 lbs [0.17 fl oz] [0.5 mL], small dogs 11 to 22.9 lbs (0.034 fl oz) [1.0 mL], medium dogs 23-44.9 lbs [0.068 fl oz] (2.0 mL), large dogs 45-88.9 lbs [0.135 fl oz] [4.0 mL], and extra large dogs 89-132 lbs (0.203 fl oz) [6.0 mL].
- EFFITIX™ Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel [against] biting flies, and repel and kill mosquitoes.
- Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, (and lice) infestations

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Helps to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

[Fleas]

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX™ Plus Topical Solution for Dogs
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills [adult] fleas
- Prevents all flea stages [adult fleas, flea eggs, flea pupae and flea larvae]
- Prevents development of all flea stages [flea eggs, flea pupae and flea larvae] for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen [IGR]* to break [the] flea life cycle
*insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis, [tularemia] [and tapeworm infestations]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [*Dipylidium caninum*]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas [within 6 hours] that may cause Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD [Flea Allergy Dermatitis]
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to [90 days] [3 months]]
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] however if your dog is susceptible to Flea Allergy Dermatitis [FAD] it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae
- EFFITIX™ Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides ongoing protection against fleas and the following diseases: bartonellosis, [tularemia] [and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents [Stops] re-infestations by killing adult fleas [before they lay eggs]
- Treatment with EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea [prevention] [protection] year-round

[Ticks]

- Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for [up to] at least [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], Brown dog ticks [that may transmit ehrlichiosis], and Lone Star ticks [that may transmit hepatozoonosis] for up to one month [4 weeks]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], and Brown dog ticks [that may transmit ehrlichiosis] for up to one month [4 weeks].
- Kills Brown dog ticks [*Rhipicephalus* spp], American dog ticks [*Dermacentor variabilis*], Deer ticks [*Ixodes* spp] and Lone Star ticks [*Amblyomma americanum*] for up to one month [4 weeks].
- Kills Lone Star ticks [*Amblyomma americanum*] for 4 weeks [or up to one month].
- Effective monthly application against ticks

[Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks] [a [one] month]
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for [up to] 4 weeks [a [one] month]
- Repels and kills mosquitoes for up to four [4] weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents [inhibits] blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [[Prevents blood-feeding by] [Kills and repels]] mosquitoes
- Repels biting flies
- Repels [[annoying][bothersome][nuisance]] biting flies
- Inhibits [[annoying][bothersome] [nuisance]] biting flies
- [[Prevents][inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos [*Culex* spp, *Ochlerotatus* spp, *Aedes* spp] (which may vector heartworm [*Dirofilaria immitis*] for one month

[Lice and Mites]

- Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for a [one] month. Apply monthly where lice control is consistently needed.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs] aids in [the] control of mites that may cause sarcoptic mange.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs] aids in [the] control of sarcoptic mites
- EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of sarcoptic mange.
- Aids in [the] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- [Also] Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills [[biting] [chewing]] lice
- For control and prevention of [[biting] [chewing]] lice [infestations]
- Stops existing [[biting] [chewing]] lice infestations
- Prevents and controls [[biting] [chewing]] lice [infestations]
- Provides effective control of [[biting] [chewing]] lice [infestations]
- Kills [[biting] [chewing]] lice and prevents further infestations
- For control and prevention of [infestation][with] [[biting] [chewing]] lice

[Others]

- 1 [3, 6, 36] applicator(s) [tube(s)] 0.5 mL [1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL]
- 1 [3, 6, 36] applicator(s) [tube(s)] 0.017 fl oz [0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz]
- 1 [3, 6, 36] applicator(s) [tube(s)] 0.017 fl oz [0.5 mL], [0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL]]
- 1 [3, 6, 36] applicator(s) [tube(s)] [each] containing 0.017 fl oz [0.5mL] [0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL]]
- 1 [3, 6, 36] applicator(s) [tube(s)]
- 1 [3, 6, 36] monthly dose(s) [application(s)]
- 1 [3, 6, 36] applicator(s) [tube(s)] f [3, 6, 36] month[ly] dose(s) [application(s)]
- DO NOT USE ON CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 11 to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs]
- Easy and convenient application [applications]
- Remains effective for a [one] month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing in/estations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, [biting, chewing] lice and biting flies is prevented for a [one] month

- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-]infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply] spot-on [topical] application
- Fragrance [odor] free
- No noticeable odors
- Single application lasts 4 weeks [one month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]
- EFFITIXTM Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof [remains effective after bathing and swimming] [for up to four weeks] [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [for a month] [for one month] [for up to four weeks]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package [applicator tubes]

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx
Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears in Brackets

EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil.....	6.0%
Permethrin*	44.8%
Pyriproxyfen.....	1.8%

OTHER INGREDIENTS: 47.4%

TOTAL: 100.0%

* cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING :	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.	

Inside flap (single presentation insert only)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labelling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs and puppies under 8 weeks of age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

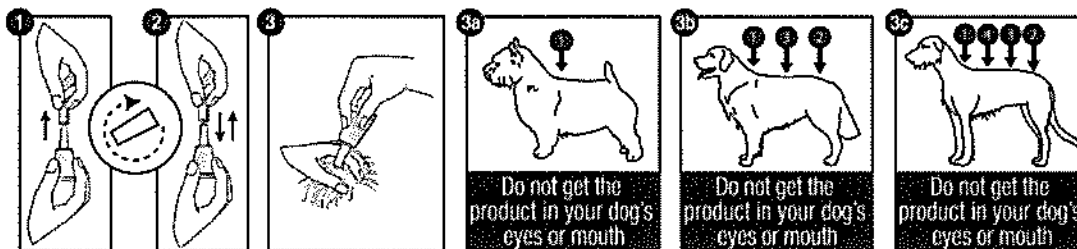
Do not apply more often than once a [per] month [every 30 days].

For use on DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs and puppies 8 weeks old or older weighing 4 to 10.9 lbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIX™ Plus Topical Solution for Dogs is not applied superficially on dog's hair.



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, (biting and chewing) and lice infestations can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are (also) repelled by EFFITIX™ Plus Topical Solution for Dogs.

Fleas: EFFITIX™ Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for (up to) three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAO), or if re-infestation is likely.

Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for (up to) a month. Apply monthly where lice control is consistently needed.

Mites: EFFITIX™ Plus Topical Solution for Dogs aids in (the) control of (sarcoptic mange)/(mite infestations that may cause sarcoptic mange).

Biting flies and Mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs (prevents blood feeding by) (and) (repels) (biting flies and mosquitoes for up to 4 weeks (a (one) month). Kills mosquitoes for up to four weeks (a (one) month).

Notes: Wait at least 30 days before re-application of EFFITIX™ Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs 11 to 22.9 lbs (0.034 fl oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.068 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1mL, 2mL, 4mL or 6mL)/ 0.017 fl oz, (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (of solution).

(Detachable) calendar (monthly application) reminder slickers (with illustration of dog or puppy)

Back Panel (single presentation on side panel)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-FRA-1

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH TX 76161
1-800-338-3659

Made in France
EFFITIX™ is a trademark of Virbac S.A.
Questions or comments? Call: 1-800-338-3659.

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application
See package insert for directions for use and storage and disposal
See package insert for frequency of application and storage and disposal
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs ONLY
Use ONLY on dogs
See inside flap for directions for use

Text for Foil of Blister package

Virbac

EFFITIX™ Plus Topical Solution For Dogs

Only for use on dogs (4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)

Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

DO NOT USE ON CATS

CAT PROHIBITION ICON

Text for Applicator Tube

Virbac

EFFITIX™ Plus

Topical Solution For Dogs

Only for use on dogs

(4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/

(0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)

Contains fipronil (6.0%), permethrin (44.8%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

DO NOT USE ON CATS

EPA Reg. No. 2382-xxx

CAT PROHIBITION ICON

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, (biting, chewing) lice, aids in the control of sarcoptic mites, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, (biting, chewing) lice, aids in the control of mites that may cause sarcoptic mange, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 4 to 10.9 lbs [0.17 fl oz] [0.5 mL], small dogs 11 to 22.9 lbs [0.034 fl oz] [1.0 mL], medium dogs 23-44.9 lbs [0.068 fl oz] [2.0 mL], large dogs 45-88.9 lbs [0.135 fl oz] [4.0 mL], and extra large dogs 89-132 lbs [0.203 fl oz] [6.0 mL].
- EFFITIX™ Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel [against] biting flies, and repel and kill mosquitoes.
- Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, (and lice) infestations

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are (also) repelled by EFFITIX™ Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Helps to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

)Fleas)

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX™ Plus Topical Solution for Dogs
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen (IGR)* to break [the] flea life cycle
*insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis, [tularemia] [and tapeworm infestations]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [*Dipylidium caninum*]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may cause Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to [90 days] [3 months]]
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] however if your dog is susceptible to Flea Allergy Dermatitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae
- EFFITIX™ Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides ongoing protection against fleas and the following diseases: bartonellosis, [tularemia] [and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)
- Treatment with EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea [prevention] [protection] year-round

[Ticks]

- Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for [up to] [at least (one) month]. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], Brown dog ticks [that may transmit ehrlichiosis], and Lone Star ticks [that may transmit hepatozoonosis] for up to one month [4 weeks]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], and Brown dog ticks [that may transmit ehrlichiosis] for up to one month [4 weeks].
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month [4 weeks].
- Kills Lone Star ticks (*Amblyomma americanum*) for 4 weeks [for up to one month].
- Effective monthly application against ticks

[Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks] [a (one) month]
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for [up to] 4 weeks [a (one) month]
- Repels and kills mosquitoes for up to four [4] weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents [inhibits] blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [[Prevents blood-feeding by] (Kills and repels)] mosquitoes
- Repels biting flies
- Repels [[annoying][bothersome][nuisance]] biting flies
- Inhibits [[annoying][bothersome]][nuisance]] biting flies
- [[Prevents][inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp) which may vector heartworm [*Dirofilania immitis*] for one month

[Lice and Mites]

- Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for a [one] month. Apply monthly where lice control is consistently needed.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs] aids in [the] control of mites that may cause sarcoptic mange.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs] aids in [the] control of sarcoptic mites
- EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of sarcoptic mange.
- Aids in [the] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- [Also] Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills [[biting] [chewing]] lice
- For control and prevention of [[biting] [chewing]] lice [infestations]
- Stops existing [[biting] [chewing]] lice infestations
- Prevents and controls [[biting] [chewing]] lice [infestations]
- Provides effective control of [[biting] [chewing]] lice [infestations]
- Kills [[biting] [chewing]] lice and prevents further infestations
- For control and prevention of [infestation](with) [[biting] [chewing]] lice

[Others]

- 1 (3, 6, 36) applicator(s) (tube(s)) 0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.017 fl oz (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.017 fl oz (0.5 mL), (0.034 fl oz (1.0 mL), 0.068 fl oz (2.0 mL), 0.135 fl oz (4.0 mL), 0.203 fl oz (6.0 mL))
- 1 (3, 6, 36) applicator(s) (tube(s)) (each) containing 0.017 fl oz (0.5 mL) (0.034 fl oz (1.0 mL), 0.068 fl oz (2.0 mL), 0.135 fl oz (4.0 mL), 0.203 fl oz (6.0 mL))
- 1 (3, 6, 36) applicator(s) (tube(s))
- 1 (3, 6, 36) monthly dose(s) (application(s))
- 1 (3, 6, 36) applicator(s) (tube(s)) 1 (3, 6, 36) month(ly) dose(s) (application(s))
- DO NOT USE ON CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 1 f to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy and convenient application [applications]
- Remains effective for a (one) month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, [biting, chewing] lice and biting flies is prevented for a [one] month

- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-]infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply] spot-on [topical] application
- Fragrance [odor] free
- No noticeable odors
- Single application lasts 4 weeks [one month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]
- EFF/TIX™ Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof [remains effective after bathing and swimming] for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [for a month] [for one month] [for up to four weeks]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package [applicator tubes]

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx
Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil.....	6.0%
Permethrin*	44.8%
Pyriproxyfen.....	1.8%

OTHER INGREDIENTS: 47.4%

TOTAL: 100.0%

* cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS


HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>Have product container or label with you when calling a poison control center or doctor, or going for treatment.</p> <p>You may also contact the Hotline number 1-800-338-3669 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.</p>	

Inside flap (single presentation Insert only)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labelling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs and puppies under 8 weeks of age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

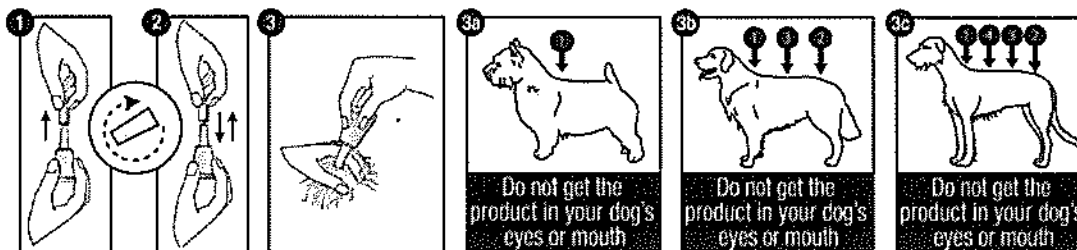
Do not apply more often than once a [per] month (every 30 days).

For use on DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part dog's hair until skin is visible.
Place applicator tip directly against exposed skin.
- 3a. For small dogs and puppies 8 weeks old or older weighing 4 to 10.9 lbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIX™ Plus Topical Solution for Dogs is not applied superficially on dog's hair.



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing] and lice infestations can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.

Fleas: EFFITIX™ Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for [up to] three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for [up to] a month. Apply monthly where lice control is consistently needed.

Mites: EFFITIX™ Plus Topical Solution for Dogs aids in [the] control of [sarcoptic mange]/[mite infestations that may cause sarcoptic mange].

Biting flies and Mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for up to 4 weeks [a [one] month]. Kills mosquitoes for up to four weeks [a [one] month].

Notes: Wait at least 30 days before re-application of EFFITIX™ Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/Toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs 11 to 22.9 lbs (0.034 fl oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.068 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1mL, 2mL, 4mL or 6mL)/ 0.017 fl oz, (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

Back Panel (single presentation on side panel)

EPA Reg. No. 2382-xxx

EPA Est. No. 2382-FRA-1

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH TX 76161
1-800-338-3659

Made in France
EFFITIX™ is a trademark of Virbac S.A.
Questions or comments? Call: 1-800-338-3659.

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application
See package insert for directions for use and storage and disposal
See package insert for frequency of application and storage and disposal
Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal
See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs ONLY
Use ONLY on dogs
See inside flap for directions for use

Text for Foil of Blister package

Virbac
EFFITIX™ Plus Topical Solution For Dogs
Only for use on dogs (4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) [0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL]
Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx
DO NOT USE ON CATS
CAT PROHIBITION ICON

Text for Applicator Tube

Virbac
EFFITIX™ Plus
Topical Solution For Dogs
Only for use on dogs
[4 to 10.9 lbs, 11 to 22.9 lbs 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs]/
[0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz] [0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)]
Contains fipronil (6.0%), permethrin (44.8%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
DO NOT USE ON CATS
EPA Reg. No. 2382-xxx
CAT PROHIBITION ICON

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, (biting, chewing) lice, aids in the control of sarcoptic mites, and repels (and inhibits blood feeding by) biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFFITIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, (biting, chewing) lice, aids in the control of mites that may cause sarcoptic mange, and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- For easy and convenient application, EFFITIX™ Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 4 to 10.9 lbs [0.17 fl oz] [0.5 mL], small dogs 11 to 22.9 lbs [0.034 fl oz] [1.0 mL], medium dogs 23-44.9 lbs [0.068 fl oz] [2.0 mL], large dogs 45-88.9 lbs [0.135 fl oz] [4.0 mL], and extra large dogs 89-132 lbs [0.203 fl oz] [6.0 mL].
- EFFITIX™ Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel [against] biting flies, and repel and kill mosquitoes.
- Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, [and lice] infestations

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIX™ Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Helps to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

[Fleas]

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX™ Plus Topical Solution for Dogs
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills [adult] fleas
- Prevents all flea stages [adult fleas, flea eggs, flea pupae and flea larvae]
- Prevents development of all flea stages [flea eggs, flea pupae and flea larvae] for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen [IGR]* to break [the] flea life cycle
*insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis, [tularemia] [and tapeworm infestations]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [*Dipylidium caninum*]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills [adult] fleas [within 6 hours] that may cause Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to] [90 days] [3 months]
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] however if your dog is susceptible to Flea Allergy Dermatitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae
- EFFITIX™ Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides ongoing protection against fleas and the following diseases: bartonellosis, [tularemia] [and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents [Stops] re-infestations by killing adult fleas [before they lay eggs]
- Treatment with EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea [prevention] [protection] year-round

[Ticks]

- Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for (up to) at least (one) month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease and anaplasmosis), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis) for up to one month (4 weeks)
- Kills ticks including Deer ticks (that may transmit Lyme disease and anaplasmosis), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks (that may transmit ehrlichiosis) for up to one month (4 weeks).
- Kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- Kills Lone Star ticks (*Amblyomma americanum*) for 4 weeks (for up to one month).
- Effective monthly application against ticks

[Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days (four weeks) (a (one) month)
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs (prevents blood feeding by) (and) (repels) biting flies and mosquitoes for (up to) 4 weeks (a (one) month)
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- (Prevents blood-feeding by) (Kills and repels) mosquitoes
- Repels biting flies
- Repels (annoying) (bothersome) (nuisance) biting flies
- Inhibits (annoying) (bothersome) (nuisance) biting flies
- (Prevents) (inhibits) blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp) which may vector heartworm (*Dirofilaria immitis*) for one month


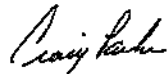
[Lice and Mites]

- Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for a (one) month. Apply monthly where lice control is consistently needed.
- Mites: (EFFITIX™ Plus Topical Solution for Dogs) aids in (the) control of mites that may cause sarcoptic mange.
- Mites: (EFFITIX™ Plus Topical Solution for Dogs) aids in (the) control of sarcoptic mites
- EFFITIX™ Plus Topical Solution for Dogs aids in (the) control of mites that may cause sarcoptic mange.
- (When applied monthly), EFFITIX™ Plus Topical Solution for Dogs aids in (the) control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of mites that may cause sarcoptic mange
- (Also) Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills (biting) (chewing) lice
- For control and prevention of (biting) (chewing) lice (infestations)
- Stops existing (biting) (chewing) lice infestations
- Prevents and controls (biting) (chewing) lice (infestations)
- Provides effective control of (biting) (chewing) lice (infestations)
- Kills (biting) (chewing) lice and prevents further infestations
- For control and prevention of (infestation) (with) (biting) (chewing) lice

[Others]


- 1 (3, 6, 36) applicator(s) (tube(s)) 0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.017 fl oz (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.017 fl oz (0.5 mL), (0.034 fl oz (1.0 mL), 0.068 fl oz (2.0 mL), 0.135 fl oz (4.0 mL), 0.203 fl oz (6.0 mL))
- 1 (3, 6, 36) applicator(s) (tube(s)) (each) containing 0.017 fl oz (0.5mL) (0.034 fl oz (1.0 mL), 0.068 fl oz (2.0 mL), 0.135 fl oz (4.0 mL), 0.203 fl oz (6.0 mL))
- 1 (3, 6, 36) applicator(s) (tube(s))
- 1 (3, 6, 36) monthly dose(s) (application(s))
- 1 (3, 6, 36) applicator(s) (tube(s)) 1 (3, 6, 36) month(ly) dose(s) (application(s))
- DO NOT USE ON CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 11 to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy and convenient application (applications)
- Remains effective for a (one) month (4 weeks) for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month

- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-]infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply] spot-on [topical] application
- Fragrance [odor] free
- No noticeable odors
- Single application lasts 4 weeks [one month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]
- EFFITIX™ Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof [remains effective after bathing and swimming] [for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [for a month] [for one month] [for up to four weeks]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package [applicator tubes]

 United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number Virbac AH, Inc./ 2382- xxx		2. EPA Product Manager Richard Gebken	
4. Company/Product (Name) EFFITIX™ PLUS Topical Solution for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Virbac AH, Inc. P.O. Box 162059 Fort Worth, TX 76161 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment – Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other – Explain below	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)			
Application for EFFITIX PLUS new product registration. PRIA Category R310. Please refer to attached letter.			
Section III			
1. Material This Product Will be Packaged in:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.5	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container 1, 3, 6 ml tubes	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic, PETE <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		5. Location of label directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section IV			
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Craig Parks, MS, DVM		Title Vice President of Research and Development, Virbac AH, Inc. Telephone No. (Include Area Code) 682-647-3576	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law			6. Date Application Received (Stamped)
2. Signature 		3. Title Vice President of Research and Development, Virbac AH, Inc.	
4. Typed Name Craig Parks, MS, DVM		5. Date August 3, 2012	

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

	United States	<input checked="" type="checkbox"/> Registration	OPP Identifier Number
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number Virbac AH, Inc./ 2382- xxx	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) EFFITIX™ PLUS Topical Solution for Dogs	PM # 10	
5. Name and Address of Applicant (Include ZIP Code) Virbac AH, Inc. P.O. Box 162059 Fort Worth, TX 76161	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ "Me Too" Application
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> Other - Explain below
<input type="checkbox"/> Notification - Explain below	

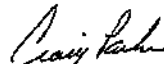
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application for EFFITIX PLUS new product registration. PRIA Category R310. Please refer to attached letter.

Section III

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic, PETE
*Certification must be submitted		If "Yes" Unit Packaging wgt. 0.5	No. per container 1,3,6,36	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1, 3, 6 ml tubes		5. Location of label directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product	
6. Manner In Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Craig Parks, MS, DVM		Title Vice President of Research and Development, Virbac AH, Inc.		Telephone No. (Include Area Code) 682-647-3576	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law					6. Date Application Received (Stamped)
2. Signature 		3. Title Vice President of Research and Development, Virbac AH, Inc.			
4. Typed Name Craig Parks, MS, DVM		5. Date August 3, 2012			

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (Original) Yellow - Applicant Copy



Virbac
ANIMAL HEALTH

VIRBAC AM INC JPMORG
Company No. 2382

JPMORGAN CHASE BANK, N.A.
2382 DALLAS, TX
88-88/1113

1016276

P.O. BOX 162059
FT. WORTH, TEXAS 76161
PH. (817) 831-5030

VOID IF NOT CASHED IN 90 DAYS

PAY

Four Thousand Eight Hundred Seven Dollars And Zero Cents

DATE _____

19-JUL-12

CHECK AMOUNT

***US DOLLARS
***4.807.00

TO THE
ORDER
OF

USEPA
C/O EXPONENT
ATTN: JIM BARRON
1150 CONNECTICUT AVE. NW, STE#1100
WASHINGTON, DC 20036
United States


AUTHORIZED SIGNATURE

AUTHORIZED SIGNATURE

C. H. Hadden
AUTHORIZED SIGNATURE

10 16 27 68



August 2, 2012

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: EFFITIX™ PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);
New Product Application.

Dear Mr. Gebken,

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382) is hereby submitting an application to register the spot-on pesticide product EFFITIX™ PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil at 6.0% w/w, permethrin at 44.8%, and pyriproxyfen at 1.8 % w/w and is intended to control fleas, ticks, mosquitoes, and other pests in dogs only.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Virbac is issuing Offer to Pay letters to the submitters of data not owned by Virbac and cited in this application that were originally submitted to EPA within the past 15 years.

Below is a list of the components included with this application:

1. Cover Letter;
2. Transmittal Document;
3. Application for Pesticide Form 8570-1 for EFFITIX™ PLUS Topical Solution For Dogs;
4. Confidential Statement of Formula for EFFITIX™ PLUS Topical Solution for Dogs;
5. Data Matrix Form 8570-4 for EFFITIX™ PLUS Topical Solution for Dogs;
6. Certification of Data Citation Form 8570-34 For EFFITIX™ PLUS Topical Solution For Dogs;
7. Proposed Use Directions for EFFITIX™ Topical Solution for Dogs - 5 copies;
8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
10. Letter of Self-certification of Child-Resistant Packaging;
11. Copy of PRIA Check for category R-310 (\$4807).

Waiver Request

Registrant: Virbac Animal Health, Inc.
Acute Inhalation Study (OPPTS 830.1300).
Brandname: EffitixTM PLUS Topical Solution for Dogs.

The Effitix PLUS Topical Solution for Dogs product is composed of 6.0% w/w of the active ingredient fipronil, 44.8% w/w of the active ingredient permethrin and 1.8% w/w of the active ingredient pyriproxifen. This product is packaged in single use non-refillable applicators that are intended for one time only spot-on applications to dogs.

The potential human inhalation exposure to this product is expected to be negligible. Only very small amounts of product are applied per application, depending the weight of the animal. Based on packaging considerations described in the proposed product labeling, the maximum volume of Effitix PLUS Topical Solution that can be administered at one time to a pet using the largest available applicator size is approximately 6.0 ml. This application volume represents the worst case because it is the dose that is recommended only for use on dogs weighing more than 89 pounds. Therefore, according to the proposed label, a great deal of anticipated product use will occur at much lower volumes on smaller dogs.

Furthermore, the measured vapor pressure of all three active ingredients fipronil, permethrin, and pyriproxifen are extremely low (2.8×10^{-9} mm Hg @ 25°C, 2.18×10^{-8} mm Hg @ 25°C, and 1.0×10^{-7} mm Hg @ 20°C, respectively) indicating that all three active ingredients are essentially non-volatile and are therefore not expected to vaporize from the skin of the treated animal following application. The active ingredients will therefore not be available for inhalation after application according to label directions. Finally, the method of applying the liquid product directly to the pet creates no particulates, aerosols, or other respirable matter. Therefore, based on the criteria provided by the Agency in 40 CFR 158.500, footnote 4 under the Toxicology Data Requirements, a waiver of the acute inhalation study for these products is appropriate.



August 3, 2012

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Child Resistant Packaging Certification
EFFITIXTM PLUS Topical Solution for Dogs;
EPA Reg. No. 2382-TBA

Dear Mr. Gebken:

I certify that the packaging used for the following product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995).

- EFFITIXTM PLUS Topical Solution for Dogs (EPA Reg. No. 2382-TBA).

Should you have any questions about this letter, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Craig Parks". The signature is fluid and cursive.

Craig Parks, MS, DVM
Vice President, Research & Development
Virbac Animal Health, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Virbac AH, Inc./ PO Box 162059 Fort Worth TX 76137/ telephone 682-647-3576	EPA Registration Number/File Symbol 2382-NEW
Active Ingredient(s) and/or representative test compound(s) Fipronil, permethrin, pyriproxyfen	Date August 3, 2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) indoor residential	Product Name EFFITIX™ PLUS Topical Solution for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
---	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

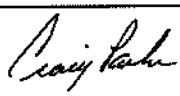
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature 	Date August 3, 2012	Typed or Printed Name and Title Craig Parks Vice President, R&D Virbac Animal Health, Inc.
---------------	------------------------	---

United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement <i>(40 CFR 152.85)</i>					
Applicant's Name and Address Virbae Animal Health P. O. Box 162059 Ft. Worth, TX 76137	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 100%;">EPA File Symbol/Registration Number 2382-NEW</td> </tr> <tr> <td>Product Name EFFITIX™ PLUS Topical Solution for Dogs</td> </tr> <tr> <td>Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012</td> </tr> </table>		EPA File Symbol/Registration Number 2382-NEW	Product Name EFFITIX™ PLUS Topical Solution for Dogs	Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012
EPA File Symbol/Registration Number 2382-NEW					
Product Name EFFITIX™ PLUS Topical Solution for Dogs					
Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012					
As an authorized representative of the applicant for registration of the product identified above, I certify that:					
(1) This product contains the following active ingredient(s): permethrin					
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.					
(3) Indicate by checking (A) or (B) below which paragraph applies:					
<input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)					
OR					
<input type="checkbox"/> (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF					
(4) The following active ingredients in this product qualify for the formulator's exemption					
Source					
Active Ingredient	Product Name	Registration Number			
Permethrin	[REDACTED]	[REDACTED]			
Pyriproxyfen	[REDACTED]	[REDACTED]			
Signature 	Name and Title Vice President, Research & Development	Date August 3, 2012			

United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement <i>(40 CFR 152.85)</i>		
Applicant's Name and Address Virbac Animal Health P. O. Box 162059 Ft. Worth, TX 76137	EPA File Symbol/Registration Number 2382-NEW Product Name EFFITIX™ PLUS Topical Solution for Dogs Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012	
As an authorized representative of the applicant for registration of the product identified above, I certify that:		
(1) This product contains the following active ingredient(s): permethrin		
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.		
(3) Indicate by checking (A) or (B) below which paragraph applies:		
<input checked="checked" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)		
OR		
<input type="checkbox"/> (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF		
(4) The following active ingredients in this product qualify for the formulator's exemption		
Source		
Active Ingredient	Product Name	Registration Number
Permethrin	[REDACTED]	[REDACTED]
Pyriproxyfen	[REDACTED]	[REDACTED]
Signature	Name and Title Vice President, Research & Development	Date August 3, 2012

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
Yellow - Applicant copy

United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement <i>(40 CFR 152.85)</i>		
Applicant's Name and Address Virbac Animal Health P. O. Box 162059 Ft. Worth, TX 76137	EPA File Symbol/Registration Number 2382-NEW Product Name EFFITIX™ PLUS Topical Solution for Dogs Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012	
As an authorized representative of the applicant for registration of the product identified above, I certify that:		
(1) This product contains the following active ingredient(s): permethrin		
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.		
(3) Indicate by checking (A) or (B) below which paragraph applies:		
<input checked="checked" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)		
OR		
<input type="checkbox"/> (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF		
(4) The following active ingredients in this product qualify for the formulator's exemption		
Source		
Active Ingredient	Product Name	Registration Number
Permethrin	[REDACTED]	[REDACTED]
Pyriproxyfen	[REDACTED]	[REDACTED]
Signature	Name and Title Vice President, Research & Development	Date August 3, 2012

EPA Form 8570-27 (Rev. 8-95)

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Yellow - Applicant copy



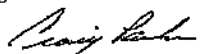
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DATA MATRIX

Date: July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 6 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and safety data -Fipronil					
810.3300	Product Performance -- Efficacy-Mange	45620504	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mange	45620505	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mange	45620506	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mites	43444901	Merial	OLD	
810.3300	Product Performance -- Efficacy-Mites	43577701	Merial	OLD	
810.3300	Product Performance -- Efficacy-Mites	43951701	Merial	OLD	
810.3300	Product Performance -- Efficacy-Mites	45612701	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mites	45620503	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mites	45866901	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45620501	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45628101	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45628102	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45628103	Merial	PAY	
810.3300	Product Performance -- Efficacy-Lice	45628201	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mosquito	45866902	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mosquito	46019202	Merial	PAY	
810.3300	Product Performance -- Efficacy-Mosquito	46019201	Merial	PAY	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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DATA MATRIX

Date July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 5 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and safety data - Fipronil					
810.3300	Product Performance - Efficacy-flea	44942106	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45618501	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45620502	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45620503	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45628104	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45628105	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45866901	Merial	PAY	
810.3300	Product Performance - Efficacy-tick	43577712	Merial	OLD	
810.3300	Product Performance - Efficacy-tick	43121114	Merial	OLD	
810.3300	Product Performance - Efficacy-tick	43121115	Merial	OLD	
810.3300	Product Performance - Efficacy-tick	43121117	Merial	OLD	
810.3300	Product Performance - Efficacy-tick	43121122	Merial	OLD	
810.3300	Product Performance - Efficacy Bathing	43121118	Merial	OLD	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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DATA MATRIX

Date: July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 4 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and safety data					
-Fipronil					
810.3300	Product Performance – Efficacy-flea	43121114	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43121115	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43121116	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43121119	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43121120	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43121121	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43121122	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43444901	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43577701	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43577712	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43577713	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43951701	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	44088901	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	44942011	Merial	PAY	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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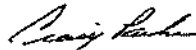
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DATA MATRIX

Date: July 31, 2012			EPA Reg. No./File Symbol 2382- TBA		Page 3 of 11
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFITIX™ TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
870.7200	Companion Animal safety 14 d pup study-1	48487302	Virbac AH, Inc	OWN	
870.7200	Companion Animal safety-Beagle Dog	48467117	Virbac AH, Inc.	OWN	
870.7200	Companion Animal safety-14 d pup study-2	48467118	Virbac AH, Inc.	OWN	
870.7200	Companion Animal safety Summary	48467119	Virbac AH, Inc	OWN	
870.7200	Companion Animal safety - Method Valid.	48467120	Virbac AH, Inc	OWN	
810.3300	Product Performance - Flea onset of Action	48510701	Virbac AH, Inc	OWN	
810.3300	Product Performance - Rhipicephalus action	48467122	Virbac AH, Inc.	OWN	
810.3300	Product Performance - D. variabilis action	48467123	Virbac AH, Inc	OWN	
810.3300	Product Performance - Shampoo study	48467124	Virbac AH, Inc	OWN	
810.3300	Product Performance - Amblyoma efficacy	48467125	Virbac AH, Inc	OWN	
810.3300	Product Performance - Ixodes efficacy	48467126	Virbac AH, Inc.	OWN	
810.3300	Product Performance - Mosquito efficacy	48467127	Virbac AH, Inc	OWN	
810.3300	Product Performance - Tick repellency	48467128	Virbac AH, Inc	OWN	
810.3300	Product Performance - Efficacy Summary	48467129	Virbac AH, Inc.	OWN	
Efficacy and Safety Data- Fipronil					
870.7200	Companion Animal safety	43444905	Merial	OLD	
870.7200	Companion Animal safety	43577711	Merial	OLD	
870.7200	Companion Animal safety	43863802	Merial	OLD	
870.7200	Companion Animal safety	43121110	Merial	OLD	
870.7200	Companion Animal safety	43121111	Merial	OLD	
870.7200	Companion Animal safety	45612702	Merial	PAY	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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DATA MATRIX

Date: July 31, 2012			EPA Reg. No./File Symbol 2382- TBA		Page 2 of 11
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry 830 Series Group B Test Guidelines					
830.7100	Viscosity	New Submission	Virbac AH, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc.	NR	
830.6320	Corrosion characteristics	To Be Conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc.	NR	
830.7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc.	OWN	
830.7320	Particle Size distribution		Virbac AH, Inc.	NR	
40 CFR 158.340 Toxicology Data Requirements					
870.1100	Acute oral toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc.	OWN	
870.1300	Acute inhalation toxicity	Waiver requested	Virbac AH, Inc.	OWN	waiver
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc.	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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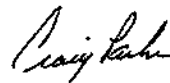
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DATA MATRIX

Date: July 31, 2012		EPA Reg. No./File Symbol 2382- TBA		Page 1 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc. PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry 830 Series Group A Test Guidelines					
830.1550	Product Identity and Composition	New Submission	Virbac AH, Inc.	OWN	
830.1600	Description of Materials Used	New Submission	Virbac AH, Inc.	OWN	
830.1620	Description of Production Process	New Submission	Virbac AH, Inc.	OWN	
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc.	OWN	
830.1670	Description of Formation of Impurities	New Submission	Virbac AH, Inc.	OWN	
830.1750	Certified Limits	New Submission	Virbac AH, Inc.	OWN	
830.1700, 830.1800	Analytical Method	New Submission	Virbac AH, Inc.	OWN	
Product Chemistry 830 Series Group B Test Guidelines					
830.6302	Color	New Submission	Virbac AH, Inc.	OWN	
830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN	
830.6304	Odor	New Submission	Virbac AH, Inc.	OWN	
830.6313	Metal Stability		Virbac AH, Inc.	NR	
830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc.	OWN	
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN	
830.6316	Explosibility		Virbac AH, Inc.	NR	
830.6317	Storage stability	To Be Conducted	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012



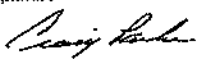
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DATA MATRIX

Date July 31, 2012			EPA Reg. No./File Symbol 2382-TBA		Page 7 of 11
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161			Product: EFFITIX TM PLUS TOPICAL SOLUTION FOR DOGS		
Ingredient: Fipronil, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRJD Number	Submitter	Status	Note
Efficacy and Safety Data- Permethrin					
870.7200	Companion Animal safety	41056906	Coopers Animal Health, Inc	OLD	
870.7200	Companion Animal safety	41953201	Coopers Animal Health, Inc.	OLD	
870.7200	Companion Animal safety	43137201	Hartz Mountain Corporation	OLD	
870.7200	Companion Animal safety	43447101	Hartz Mountain Corporation	OLD	
870.7200	Companion Animal safety	43396408	ECTO Development Corporation	OLD	
870.7200	Companion Animal safety	43612601	ECTO Development Corporation	OLD	
810.3300	Product Performance - Efficacy	41038802	Cooper's Animal Health	OLD	
810.3300	Product Performance - Efficacy	41038803	Cooper's Animal Health	OLD	
810.3300	Product Performance - Efficacy	43137202	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43137203	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	46006002	Wellmark	PUB	
810.3300	Product Performance - Efficacy	41683903	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43111607	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy-Biting Fly	46978901	Bayer Healthcare LLC	PAY	11-13-06
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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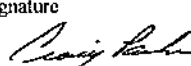
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DATA MATRIX

Date: July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 8 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data- Permethrin					
810.3300	Product Performance - Efficacy	42256901	Cooper's Animal Health, Inc.	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
Efficacy and Safety Data- Pyriproxifen					
870.7200	Companion Animal Safety	43396408	Ecto Development Corporation	OLD	
870.7200	Companion Animal Safety	43612601	Ecto Development Corporation	OLD	
870.7200	Companion Animal Safety	44900902	Virbac AH, Inc.	OWN	
870.7200	Companion Animal Safety	44900903	Virbac AH, Inc.	OWN	
870.7200	Companion Animal Safety	42178309	Sunitomo Chemical Company, Ltd.	OLD	
810.3300	Product Performance - Efficacy	44900904	Virbac AH, Inc.	OWN	
810.3300	Product Performance - Efficacy	45020601	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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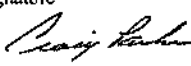
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DATA MATRIX

Date: July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 9 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant Packaging					
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 1 applicator tube test as a Poison Prevention Package for Virbac SA	48467130	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467131	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 6 applicator tubes test as a Poison Prevention Package for Virbac SA	48467132	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbac	48467133	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 1 applicator tube test as a Poison Prevention Package for Virbac SA	48467134	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467135	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 6 applicator tubes test as a Poison Prevention Package for Virbac SA	48467136	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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DATA MATRIX

Date: July 12, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 10 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbac SA	48467137	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 1 applicator tube test as a Poison Prevention Package for Virbac SA	48467138	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467139	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 6 applicator tubes test as a Poison Prevention Package for Virbac SA	48467140	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbac SA	48467141	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 1 applicator tube test as a Poison Prevention Package for Virbac SA	48467142	Virbac AH, Inc.	OWN	Vol 43
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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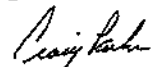


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DATA MATRIX

Date: July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 11 of 11	
Applicant's/Registrant's Name & Address Virbac AH, Inc PO Box 162059 Fort Worth TX 76161		Product: EFFITIX™ PLUS TOPICAL SOLUTION FOR DOGS			
Ingredient: Fipronil, Permethrin, Pyriproxifen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467143	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 6 applicator tubes test as a Poison Prevention Package for Virbac SA	48467144	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbac SA	48467145	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095215	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicator tubes test for Child-Resistant Effectiveness	48095216	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicator tubes test for Child-Resistant Effectiveness	48095217	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095218	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicator tubes test for Senior-Use Effectiveness	48095219	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicator tubes test for Senior-Use Effectiveness	48095220	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.50 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410018	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.50 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410019	Virbac AH, Inc.	OWN	
Signature 			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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Virbac Effitix Plus
8/2/12

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac Animal Health, Inc. (EPA Company Number 2382)
P.O. Box 162059
Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use product named EFFITIX™ Plus Topical Solution for Dogs.

SUBMITTAL DATE:

August 2, 2012

Volume	Study Name (Lab Reference Number)	MRID
TRANSMITTAL DOCUMENT		48896300
1	Product Specific Chemistry For Effitix™ Plus Topical Solution for Dogs	48896301
2	Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxifen in Five Batches by Validated Methods	48896302
3	Determination of the physic-Chemical Property Appearance (Color, Physical State, and Odor) (D42327)	48896303
4	Determination of Oxidation/reduction: Chemical Incompatability (D42305)	48896304
5	Determination of the Physico-Chemical Property "Flash Point" (D42316)	48896305
6	Determination of the Physico-Chemical Property Viscosity (D42272)	48896306
7	Determination of the Physico-Chemical Property pH (D42294)	48896307
8	Determination of the Physico-Chemical Property Relative Density (D42283)	48896308
9	Acute oral toxicity (D42171)	48896309
10	Acute dermal toxicity (D42182)	48896310
11	Primary eye irritation (D42193)	48896311
12	Primary dermal irritation (D42202)	48896312
13	Dermal sensitization (D42215)	48896313
14	Summary of Efficacy Data For Effitix™ Plus Topical Solution for Dogs	48896314
15	Summary of Companion Animal Safety Data For Effitix™ Plus Topical Solution for Dogs	48896315

